Thursday 2nd June, 2022

Dear Tribunal,

I would like to submit below a few comments on the Commissioner's Response and the MHRA Response as drafted by Ms Jennifer Thelen. I have also read the witness statement by Dame June Raine. The latter document largely reiterates the rationales expressed in the former documents. However, at the end of this response I will give a reply to one original point raised by Dame June Raine.

At Par. 18 and 19 the Commissioner reiterates the argument that publication of the requested data without context would be against public interest, and that it is therefore reasonable to expect that the MHRA would delay publication for two years to prepare contextual information. This should be contrasted to the body of data and accompanying contextual information on vaccine effectiveness that the UK Health Security Agency (UKHSA) – formerly Public Health England (PHE) – has been publishing since September 2021. Their contextual information appeared in November 2021 (https://ukhsa.blog.gov.uk/2021/11/02/transparency-and-data-ukhsas-vaccines-report/), which concludes with the following paragraph (emphasis is mine):

> We believe that **transparency** - coupled with explanation – remains the best way to deal with misinformation. UKHSA has been committed to regular publishing of our vaccine effectiveness data and sharing this evidence **promptly** with others – this has played a huge role in increasing vaccine confidence in this country and worldwide.

It is interesting to note that the UKHSA data analyses on vaccine effectiveness have been a relatively new venture for the agency. Nonetheless, their contextual information has been immediately forthcoming, amounting to a couple of pages of clear explanations. The MHRA has been managing the Yellow Card Scheme since 1964, and still we have no contextual information and prompt transparency about the adverse reaction data related to a handful of individual vaccines arrived on the market more than a year ago.

Also, at Par. 19 the Commissioner again reiterates a previous argument that the MHRA does not have to commit to a specific date for releasing the requested data. However, the MHRA historical duty as Government institution designated to oversee drug safety has been to publish data of adverse reactions to all drugs and vaccines within less than two months of the reactions being reported. While Section 22 of the FOIA does not oblige the MHRA to commit to a specific data publication date, the MHRA own statutory role does.

At Par. 2 Ms Thelen states that "given the significance of vaccines in managing the COVID-19 pandemic, and the sensitivity around their use, the public interest favours maintaining the exemption, to allow the MHRA to publish the requested information in accordance with a plan designed to manage these very risks." The argument of the vaccine "significance" in managing the pandemic does not support maintaining the exemption. Indeed, there are a handful of drugs already on the market which have much higher significance in decreasing mortality rates in the general population than the Covid-19 vaccines, e.g., antihypertensive drugs, antihypercholesterolaemic drugs, or key chemotherapy agents. Adverse drug reaction data for these drugs is readily available, despite these drugs preventing or curing diseases that have an impact on mortality far greater than Covid-19 has had on the general population, and especially the older population. How can then the Commissioner and MHRA agree that timely

publishing adverse drug reaction data for Covid-19 vaccines would be more “risky” than timely publishing the respective data for drugs which are much more widely used and taken by millions of individuals for several years of one’s life to prevent or cure diseases with much higher mortality rate than Covid-19 mortality rate? In essence, neither the Commissioner nor the MHRA have been able to provide any relevant arguments to justify treating the publishing of adverse drug reactions from Covid-19 vaccines differently from those arising from other drugs.

In addition, at Par. 7 Ms Thelen echos the argument that the Commissioner brought forward in relation to the MHRA already publishing ‘Vaccine Analysis in Print’. As I have pointed out before, these analyses are what they are, just analyses, and do not provide the raw data as I requested and as they are timely provided for all other drugs. I have also already raised the issue that these analyses, by providing as the only raw data the absolute numbers of reactions, do indeed run the risk of fueling misinterpretation of the figures, since they lack the context that the rest of the related data (age, sex, etc.) would provide. The MHRA would reduce this risk by following in the UKHSA footsteps, thereby providing all data no soon it becomes available, along with clear and concise explanation of remit and limitation of the figures.

At Par. 12e and Par 18e Ms Thelen makes reference to the Japanese case of the human papillomavirus vaccination programme. In the latter paragraph she maintains that this case shows that “there is concrete evidence of the risks of misinformation about vaccines” and that “this [case] is clear and compelling evidence of the risks of public misinformation impacting on a vaccination campaign.” I refer to my appeal letter date 5 February 2022 at the paragraph titled ‘Against the argument that misinterpretation of the released data could undermine the Covid-19 vaccination programme’, where I provide a full rebuttal of the Japanese example as being supportive of the MHRA and the Commssioner’s decision of withholding the requested data. To summarise here my key argument therewith expanded, the Japanese case only demonstrates the risk of a government choosing not to promote a vaccine programme, and not how a rogue article can undermine public confidence. Of the latter argument there is no evidence in the literature, and it stems solely from the MHRA’s incorrect analysis of the Japanese case.

At Par. 18e Mr Thelen brings forward the case of the fears over the MMR vacccine as a further example of the vaccine misinformation risk that would be incurred should adverse drug reaction data for Covid-19 vaccines were published. Again, as for the Japanese case, this example is not apt, and in fact, is an argument against withholding the data I requested. Ms Thelen herself points out that the MMR “scare” was related to “fraudulent data”, not to fraudulent analysis or misinterpretation. The MMR case was a case of falsification of data to arrive at wrong conclusions with a correct method of analysis. In the present FOI case my request is precisely to obtain the reliable data that the MHRA holds, which, as an added benefit, would undermine any attempt of rogue scientists to fabricate their fraudulent data. Any article based on the real data that the MHRA could provide would give, as it is customary in research papers, a description of the analysis method used, which then anyone with relevant abilities, armed also with the original MHRA data, could replicate and then arrive, hopefully, at similar results. Indeed, in scientific research, it is easier to hide behind fabricated data then behind the method of analysis. Ms Thelen has it the wrong way round; the fact is that making available in a timely fashion the reliable Covid-19 vaccine adverse drug reaction data from the MHRA would undermine rogue scientists, rather than undermine the vaccination programme.

In Par. 18a-c and 18i-k Ms Thelen provides an exposition around the MHRA SafetyConnect system as a new major investment programme to upgrade its safety reporting system. This provides information of a new golden plated system that will soon be ready to provide all the data I requested and more. This

certainly is not an argument for not publishing the requested data in the old format while waiting for the new one. If I am waiting to receive in the post an upgrade for my old mobile phone, I do not stop making calls – i.e. sending/receiving audio data – or corresponding with text messages – i.e., sending receiving text data – but I continue to use my old mobile phone until the new one arrives, as this data is important to me. Similarly, as the publication of adverse drug reaction data has been considered by the MHRA worthy of timely publication for all drugs and vaccines in the old system, this can continue while waiting for the new system even for Covid-19 vaccine data.

At Par. 18f Ms Thelen states that the VAERS example is not an apt comparison, citing the different privacy law governing the US pharmacovigilance system. Unfortunately, Ms Thelen has missed completely the aim of illustrating the VAERS example. Citing VAERS was not to imply that the MHRA should follow the US example from the point of view of data management policies. The point of considering the VAERS example was to show how the timely publication of extensive Covid-19 vaccine adverse drug reaction raw data has not affected the efficacy of the vaccine programme in the US, hence showing that the MHRA should not fear of undermining the vaccine programme through publication of the raw data it keeps. This argument is developed with greater details in my appeal letter dated 5 February 2022 at the paragraph titled ‘Against the argument that misinterpretation of the released data could undermine the Covid-19 vaccination programme’.

In regards to the witness statement, Dame June Raine states that, in any case, vaccine reaction data are not available through the interactive Drug Analysis Profiles (iDAPs) repository. This is technically true, but the MHRA still promises to provide this data to whom specifically requests it, hence my original request more than a year ago. Indeed, the iDAP web page states that “Information regarding suspected adverse reactions to vaccines is not currently available via the iDAPs **but is available upon request** [emphasis is mine]” (https://yellowcard.mhra.gov.uk/idaps). Then, Dame June Raine should arrange for the following caveat to be added to the note: “… However, requests of suspected adverse reactions to Covid-19 vaccines will not be fulfilled”, and include as justification a link to the 238 pages of her statement (including attachments) to explain the exemption to interested members of the public like me. Incidentally, it is revealing that, while the MHRA will need at least two years to produce for the public at large a “contextual narrative” to accompany the publication of Covid-19 vaccine adverse reaction data, it has taken to the MHRA and a governmental legal team only a few months to produce hundreds of pages providing a “rationale narrative” to prevent the publication of this very data. It shows that more effort is being spent to prevent the publication of the data than to publish it.

In conclusion, the rationales provided by the Commissioner, the MHRA and its legal team are weak at best in their attempt to support an exemption towards publishing the data I requested. The MHRA should follow the UKHSA statement I quoted at the start of this reply, where prompt transparency coupled with prompt explanation is “the best way to deal with misinformation.” Unfortunately, the MHRA decision to be silent on the actual Covid-19 adverse reaction data projects an aura of censorship that fuels conspiracy theories rather than preventing them.

Marco Tullio Suadoni

IN THE FIRST TIER TRIBUNAL **EA/2022/0039**
(GENERAL REGULATORY CHAMBER)
INFORMATION RIGHTS
UNDER SECTION 57 OF THE FREEDOM OF INFORMATION ACT 2000

B E T W E E N:

MARCO TULLIO SUADONI

APPELLANT

-and-

INFORMATION COMMISSIONER

FIRST RESPONDENT

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

SECOND RESPONDENT

RESPONSE TO APPEAL
on behalf of the Second Respondent

Introduction

1. The Appellant Marco Suadoni (the "**Appellant**") has requested information about suspected adverse reactions to COVID-19 vaccines. The Second Respondent the Medicines and Healthcare products Regulatory Agency (the **"MHRA**") has withheld the information responsive to his request, on the basis that it intends to publish it at a future date. The Information Commissioner (the "**Commissioner**") has issued a decision notice, dated 26 January 2022 (the "**Decision Notice**") agreeing with the MHRA that it is entitled to withhold the requested information under section 22(1) of the Freedom of Information Act 2022 ("**FOIA**") and the public interest favours maintaining the exemption.

2. The dispute between the parties is around whether the public interest favours maintaining the exemption. Here, it plainly does. Releasing the withheld

information outside of the MHRA's planned publication scheme would mean releasing it without the communication materials and appropriate safeguards designed to manage the misuse of data and to mitigate risks associated with the misinterpretation of the data. In order to ensure that the risks outlined in the MHRA response to the ICO are appropriately safeguarded against, the new format established though the SafetyConnect programme, is being created iteratively. This will deliver a new modern vigilance database and the contextual narrative surrounding it for COVID-19 vaccines. This is a work in progress by the MHRA with anticipated further independent review by internal and external stakeholders, the Vaccine Benefit Risk Expert Working Group and the Commission on Human Medicines over the coming months to enable publication by the end of 2022. Given the significance of vaccines in managing the COVID-19 pandemic, and the sensitivity around their use, the public interest favours maintaining the exemption, to allow the MHRA to publish the requested information in accordance with a plan designed to manage these very risks.

3. The MHRA, then, opposes the appeal, and maintains that it should be dismissed.

4. This response is served in accordance with Rule 23 of the *Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009* (the "**2009 Rules**") and pursuant to the 8 April 2022 Case Management Direction of this Tribunal.

Factual Background

Adverse Reaction Reporting

5. The MHRA maintains a "Yellow Card" scheme.[1] Through this scheme, members of the public and healthcare professionals voluntarily submit reports of suspected side effects to the MHRA. Drug companies also submit such reports as part of their legal requirements. The "Yellow Card" website is one way in which the MHRA collects and monitors information on safety concerns such as suspected side effects

[1] https://coronavirus-yellowcard.mhra.gov.uk/

or adverse incidents involving medicines and medical devices. Data can also be collected and monitored through the app, some clinical IT systems and by phone.

6. Interactive Drug Analysis Profiles (or **"iDAPs**") for a wide range of medicines on the Yellow Card website[2] contain data for all spontaneous suspected adverse drug reactions, or side effects, which have been reported on that drug substance to the MHRA via the Yellow Card scheme, from healthcare professionals and members of the public. iDAPs enable people to interact with the data so they can understand more about the types of suspected adverse reactions that have been reported and, at a high level, about who experienced the suspected side effects. The iDAP for each medicine featured on the Yellow Card website report against a number of factors: sex, age group, year received, reporter, route of administration, seriousness and system organ class.

7. However, COVID-19 vaccines and medicines have their own Yellow Card reporting site.[3] Individuals can submit a suspected adverse reaction report about a COVID-19 vaccine but are not able to access the same detailed iDAP data that is available for other medications. A weekly summary report of suspected adverse reactions associated with approved COVID-19 vaccines is published, together with a PDF drug analysis profile (or "**DAP**") containing a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme for the COVID-19 Pfizer/BioNTech Vaccine, the Covid-19 Vaccine AstraZeneca, the COVID-19 Vaccine Moderna and where the brand of the vaccine was not specified (referred to as the "*Vaccine Analysis Print*").[4] Further, the weekly report provides exposure data which provide figures per million doses which further helps to illustrate that the reporting rates of many of the more serious suspected ADRs are very low in the context of the numbers of vaccine doses administered.

[2] https://yellowcard.mhra.gov.uk/idaps
[3] https://coronavirus-yellowcard.mhra.gov.uk/
[4] https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

8. The MHRA is currently preparing the iDAP data associated with the COVID-19 vaccines for publication. The MHRA expects to publish the data in question by the end of 2022. The MHRA's explanation for this timeframe is explained in detail at paragraph 18.g below.

Request

9. On 19 March 2021, the Appellant wrote to the MHRA with the following request (the "**Request**"):

> "First of all, I am aware of the information available here: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions
>
> However, the information linked as above does no report all ADRs data, but only summary data. I request in spreadsheet or database format, e.g. comma-separated-values (CSV) (not PDF format), the full body of all anonymised raw data with the level of details as close as possible to that one available for Interactive Drug Analysis Profile (IDAP) and related CSV files, for all Covid-19 vaccines currently in use in the UK.
>
> Especially to include for EACH event, but not limited to:
>
> SEX
> AGE
> DATE
> REPORTER
> REPORT SUBMISSION
> ROUTE OF ADMINISTRATION
> SERIOUSNESS
> SYSTEM ORGAN CLASS."

10. On 19 April 2021, the MHRA wrote to the Appellant, refusing to disclose the information under s.22 of FOIA. The MHRA explained that it intended to publish all suspected reactions reported in association with available COVID-19 vaccines in an interactive format as interactive Drug Analysis Profiles, or (iDAPs), along with the Adverse Drug Reaction ("**ADR**") summary that is published each week. The MHRA explained that the use of iDAPs will enable users to view the data by categories of their choice, such as age, sex and seriousness of reports.

11. Following an internal review on 12 May 2021, the MHRA wrote to the appellant, maintaining its position that it was entitled to withhold the requested information under section 22 FOIA.

12. The Appellant complained to the Commissioner, and the Decision Notice followed. In the Decision Notice the Commissioner:

    a. notes that he was "*satisfied that, at the time of the [Request] the MHRA held the data with a view to publishing it at a future date*"; [Decision Notice ¶19]

    b. found that it was reasonable in all the circumstances to withhold the requested information, taking into account the risks associated with publishing the information in its current form, and the fact that the MHRA is developing a route to publication that will allow it to mitigate the risks identified, including developing extensive communication materials to manage the misuse of data, to mitigate any risks associated with misinterpretation of data and to manage the resources associated with publishing data; [Decision Notice ¶¶21-4]

    c. noted specifically that this approach was in line with the MHRA's practice to provide a clear context against each reported suspected adverse reaction; [Decision Notice ¶34]

    d. noted the basis on which the Appellant put the public interest in disclosure, including that the data "originates with the public", transparency and that he considers that the release of the data would allow it to be analysed by independent researchers, in parallel to the MHRA's efforts; [Decision Notice ¶28]

    e. found that this was, however, outweighed by the public interest in maintaining the exemption, namely that releasing data in this way could undermine "*the wider Government public health exemption for widespread Covid-19*." This included "*the disbenefit of publishing the data without context; the potential for misinterpretation and misuse of sporadic and isolated reports; and the*

potential subsequent tangible harm", namely a risk to public health and safety. [Decision Notice ¶¶30; 33] The Commissioner recognised the example provided by the MHRA, of the termination by the Japanese Government of a human papillomavirus vaccine programme following misinterpretation of published data, which has the potential to result in a significant number of deaths from cervical cancer which would otherwise have been prevented. [Decision Notice ¶31]

f. Specifically, the Commissioner stated:

> "He fully appreciates the strong public interest there was, and is, in the COVID-19 vaccines and any adverse reactions people may have experienced after having received one. However, given the significance of the vaccines and the sensitivities surrounding them, the Commissioner considers that there is stronger public interest in MHRA being able to publish the iDAP data for the vaccines in line with its planned timetable. This will ensure that MHRA has had the time it needs to consider the risks associated with publishing this information; how best to present the information alongside context and guidance so as to minimise the risk of the information being misinterpreted or misused. That is a complex process." [Decision Notice ¶35]

Legal Background

13. Section 22(1) of FOIA provides:

> "(1) Information is exempt information if –
>
> (a) the information is held by the public authority with a view to its publication, by the authority or any other person, at some future date (whether determined or not),
>
> (b) the information was already held with a view to such publication at the time when the request for information was made, and
>
> (c) it is reasonable in all the circumstances that the information should be withheld from disclosure until the date referred to in paragraph (a).
>
> (2) The duty to confirm or deny does not arise if, or to the extent that, compliance with section 1(1)(a) would involve the disclosure of any information (whether nor not already recorded) which falls within subsection (1)."

14. Section 22 is a qualified exemption which means it is subject to a public interest test.

15. In his guidance and response to this Appeal, the Commissioner has set out four questions to be asked:

    a. First, is there an intention to publish the requested information at some future date?

    b. Was the information already held with a view to publication at the time the request was made?

    c. Is it reasonable to withhold the information from disclosure until the intended date of publication?

    d. Does the public interest in maintaining the exemption outweigh that in disclosing the exemption?[5]

16. In considering the public interest in disclosure, it is appropriate to consider both the harm arising from early disclosure ahead of the scheduled release date, as well as harm arising out of the context in which information is disclosed. Queen Mary University London v Information Commissioner (EA/2012/0229) (26 September 2012) (at para.9).

Grounds of Appeal

17. The basis of the appeal is that the Appellant disagrees with the Commissioner's conclusions on the balance of the public interest. Specifically he argues:

    a. The Commissioner placed too much weight to the concerns raised around misinterpretation of data, and the negative impact that could have on the COVID-19 vaccination campaign;

    b. Two years is too long to wait for the MHRA to provide the contextual information to accompany the data; and

[5] ICO Guidance, Information intended for future publication and research information, ¶¶5;22; and 28; ICO Response to the Appeal ¶6.

c. There is a public interest in the timely publication of the requested information.

18. Addressing these arguments, the MHRA maintains that the public interest balance favours maintaining the exemption:

a. There is a strong public interest in MHRA publishing the iDAP data in line with its timetable. Publishing the iDAP data in this way allows the MHRA to mitigate the risks associated with publication of raw vaccine data.

b. The MHRA is undertaking a major investment programme to upgrade its safety reporting systems via its Safety Connect programme. Its SafetyConnect programme is using new technology to improve its responsiveness to patients. It will deliver a new modern vigilance database using artificial intelligence to support the more rapid identification of safety signals across medicines, medical devices, blood products and also product quality defects. Throughout the development of the new system, the MHRA has engaged with patients and the public directly to gain user feedback and perceptions on the system via user needs sessions.

c. The work is now at an advanced stage of testing prior to full implementation and the SafetyConnect programme will continue to enhance the service over the coming months. A new Yellow Card website went live in February 2022, building on the improvements made to the Coronavirus Yellow Card site that was deployed in May 2020 and enhanced throughout the pandemic. Other recent enhancements include installing new functionality that enables patients to update their own reports and the MHRA to raise requests for additional information from reporters to aid the ongoing assessment of their reports. These changes have enabled integration of Yellow Card into other services such as the NHS App and will make the Yellow Card scheme more informative with new information presented to users by the end of 2022.

d. There is a disbenefit of publishing the data without context. Publishing the raw data increases the potential for misinterpretation, and in particular misuse of sporadic and isolated reports.

e. Here, there is concrete evidence of the risks of misinformation about vaccines. The MHRA has pointed to the HPV vaccination programme in Japan as clear evidence of the risks of a harm to public health following misinformation about a vaccination programme. There, the Japanese government ceased funding, and recommending, the HPV vaccination following concerns being raised about its safety. Those concerns were unfounded. Rates of HPV have increased in Japan for the generation of women who were not vaccinated over this period. In particular, a study in the Lancet found that the policy to stop recommending this vaccine will likely result in almost 11,000 deaths from cervical cancer if not reversed. By way of further example, fraudulent data led to a fear over a false association between MMR vaccination rates and health consequences, which led to a significant reduction in MMR vaccination rates in the UK.[6] This is clear and compelling evidence of the risks of public misinformation impacting on a vaccination campaign.

f. The Appellant raises the example of the VAERS system in the United States. However, that is not an apt comparison. Privacy and data protection laws are different in the United States and allow for release of different information. More fundamentally, the MHRA has agreed that it will publish the data at the core of the Appellant's request; the question here is simply around timing.

g. Publication in accordance with the set timeframe will ensure that the MHRA has the time it needs to consider the risks associated with publishing this information. It also ensures that the MHRA has the time to consider how best to respond to these risks. For example, the MHRA will have an opportunity to contextualise the information (including, for example, exposure data), and provide guidance, so as to minimise the risk of the information being

[6] https://www.bmj.com/content/342/bmj.c7452 [See Annex 1 to this submission]

misinterpreted or misused. The Commission on Human Medicines ("CHM") will also be involved as co-owner of the Yellow Card scheme.

h. The MHRA is developing a more appropriate route to publication; it has committed to publishing the requested information by the end of 2022. By this time, the MHRA will begin implementing new systems for the provision of data across all medical products including vaccines. In order to ensure that the risks outlined in the MHRA response to the ICO are appropriately safeguarded against, a new modern vigilance database through the SafetyConnect programme and the contextual narrative surrounding it for COVID-19 vaccines is being created iteratively. This is a work in progress by the MHRA with anticipated further independent review by internal and external stakeholders, the Vaccine Benefit Risk Expert Working Group and the Commission on Human Medicines over the coming months to enable publication by the end of 2022.

i. Alongside the raw data, there will be communication materials to manage the misuse of data and mitigate any risks associated with the misinterpretation of the data as well as to enable accurate interpretation of the data to provide additional reassurance.

j. The Appellant suggests that this information can be published more quickly because it is "*nothing out of the ordinary*". [Grounds of Appeal, p.2]

k. This is not correct. As recognised by the Commissioner, this is a complex process. [ICO Response ¶19] This task is made more complex by the fact the MHRA is altering the way in which it presents the Yellow Card iDAPs, as explained above. Only when those changes are complete will the MHRA be in a position to publish the vaccine iDAPS. This process is built into the time frame, and current estimate of the end of 2022. It would not be reasonable to prepare the materials for presentation in two formats – the old format and the new format, due to the time and cost involved. Further, publishing to a quicker timescale would not leave time to consult with relevant stakeholders,

such as the Vaccines Benefit Risk Expert Working Group, Commission on Human Medicines and multiple stakeholders.

l. Safety information on COVID-19 vaccines has already been the subject of misinformation. It is vitally important to provide Yellow Card data in a way that makes clear the limitations and uncertainties and has the appropriate caveats to support interpretation of Yellow Card data. The risk of misinformation arises without it. Plainly, there is a risk of adverse public health outcomes if the published data are misinterpreted, and that misinterpretation results in a reduced take-up of COVID-19 vaccines. The MHRA maintains that significant weight should be given to the risk that early publication could undermine the wider Government public health campaign for widespread COVID-19 vaccination.

m. The Appellant also states that iDAPs are reported for similar drugs, which are subject to additional monitoring and are under conditional marketing authorisation, such as Brentuximab. [Grounds of Appeal, p.3] This is not an apt comparison. As explained above, there are particular concerns around the impact of misinformation and confusion about COVID-19 vaccines, given both the sensitivity around the vaccines and their key role in managing the COVID-19 pandemic.

n. The Appellant appears to suggest that there is a current risk arising out of the lack of context with which the MHRA currently provides its weekly COVID-19 reports. That is incorrect. The current ADR reporting specifically includes a detailed narrative around context, and advice on the overall safety of the approved COVID-19 vaccines (as explained at paragraph s below).

o. The Appellant argues that review and analysis of the vaccination data outside of the MHRA, and by means other than the MHRA algorithm, are said to provide an additional measure of public security. However, iDAP data releases do not support data for research purposes. They would need to be more detailed, and follow a scientific protocol agreed by the

Pharmacovigilance Expert Advisory Group. iDAP data (and the current ADR reporting) is made available purely for transparency purposes. In any event, it is clear that this data will be released. However, the MHRA maintains that the risks associated with the publication of raw data without proper context and explanation are serious and justify publication in accordance with the timeline it has set.

p. There is no requirement, within section 22, to commit to a specific future publication date. [ICO Response ¶19] However, the MHRA has confirmed that the requested information will be published, subject to there being no unforeseen delays to the rollout of the new scheme, by the end of 2022.

q. The MHRA is committed to transparency. This is demonstrated by the publication of the COVID-19 vaccines ADR summary, whereby data sets for suspected adverse drug reactions which have been reported to the MHRA are published alongside the MHRA's assessment of the data.

r. The MHRA recognises there is a strong public interest in understanding the benefits and risks of COVID-19 vaccines, and any suspected adverse reactions experienced after receiving a vaccine.

s. Pending publication of the requested information, detailed information is being published in the form of a weekly summary COVID-19 vaccine ADR report.[7] These reports detail doses administered and Yellow Card reporting trends, and provide an analysis of the data, including safety data. The safety data includes an analysis of the safety risks for specific groups, such as pregnant people and children, and on specific topics, such as anaphylaxis and transverse myelitis. Thus, in these reports, the ADR data are included in a narrative designed to provide context and information to members of the

[7] https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

public seeking out information about the risks of an adverse reaction to a vaccine.

t. Attached to the weekly report is a COVID-19 vaccine analysis print, for each authorised vaccine. The report lists all UK spontaneous reports received up to that point. Thus, for the Moderna vaccine, 4 reports of a "Cardiac conduction disorder/atrioventricular block" are reported.[8]

u. Therefore, there continues to be information available to the public about ADR reports regarding COVID-19.

19. In these circumstances, the MHRA maintains that the public interest plainly favours maintaining the exemption, to allow for publication in accordance with its scheme.

20. In the Grounds of Appeal the Appellant does not dispute the engagement of section 22(1). Thus, it appears accepted that:

a. the MHRA has a future intention to publish the requested information;

b. the MHRA had a settled intention to publish the requested information prior to the request being received; and

c. the intention to withhold the requested information was reasonable in all the circumstances (recognising that the Appellant does dispute reasonableness in the context of the public interest balancing test).

21. To the extent any of these elements remain disputed, the MHRA relies on the reasoning in the Decision Notice.

Form of Hearing

22. The Appellant has stated that he prefers a paper hearing of this appeal. The Commissioner agrees that this mode of hearing is appropriate. The Second

8 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1072045/COVID-19_vaccine_Moderna_analysis_print.pdf

Respondent agrees that a paper hearing is a proportionate way to deal with this matter, and also consents to this matter being dealt with on the papers.

Jennifer Thelen

39 Essex Chambers

18 May 2022

ANNEX 1

thebmj

Editorials

Wakefield's article linking MMR vaccine and autism was fraudulent

BMJ 2011; 342 doi: https://doi.org/10.1136/bmj.c7452 (Published 06 January 2011) Cite this as: BMJ 2011;342:c7452

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Clear evidence of falsification of data should now close the door on this damaging vaccine scare

"Science is at once the most questioning and . . . sceptical of activities and also the most trusting," said Arnold Relman, former editor of the *New England Journal of Medicine*, in 1989. "It is intensely sceptical about the possibility of error, but totally trusting about the possibility of fraud."**1** Never has this been truer than of the 1998 *Lancet* paper that implied a link between the measles, mumps, and rubella (MMR) vaccine and a "new syndrome" of autism and bowel disease.⇓

EARLY REPORT

Early report

Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

A J Wakefield, S H Murch, A Anthony, J Linnell, D M Casson, M Malik, M Berelowitz, A P Dhillon, M A Thomson, P Harvey, A Valentine, S E Davies, J A Walker-Smith

Summary

Background We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder.

Methods 12 children (mean age 6 years (range 3–10), 11 boys) were referred to a paediatric gastroenterology unit with a history of normal development followed by loss of acquired skills, including language, together with diarrhoea and abdominal pain. Children underwent gastroenterological, neurological, and developmental assessment and review of developmental records. Ileocolonoscopy and biopsy sampling, magnetic-resonance imaging (MRI), electroencephalography (EEG), and lumbar puncture were done under sedation. Barium follow-through radiography was done where possible. Biochemical, haematological, and immunological profiles were examined.

Findings Onset of behavioural symptoms was associated, by the parents, with measles, mumps, and rubella vaccination in eight of the 12 children, with measles infection in one child, and otitis media in another. All 12 children had intestinal abnormalities, ranging from lymphoid nodular hyperplasia to aphthoid ulceration. Histology showed patchy chronic inflammation in the colon in 11 children and reactive ileal lymphoid hyperplasia in seven, but no granulomas. Behavioural disorders included autism (nine), disintegrative psychosis (one), and possible postviral or vaccinal encephalitis (two). There were no focal neurological abnormalities and MRI and EEG tests were normal. Abnormal laboratory results were significantly raised urinary methylmalonic acid compared with age-matched controls (p=0·003), low haemoglobin in four children, and a low serum IgA in four children.

Interpretation We identified associated gastrointestinal disease and developmental regression in a group of previously normal children, which was generally associated in time with possible environmental triggers.

Lancet 1998; **351:** 637–41
See Commentary page 611

Introduction

We saw several children who, after a period of apparent normality, lost acquired skills, including communication. They all had gastrointestinal symptoms, including abdominal pain, diarrhoea, and bloating and, in some cases, food intolerance. We describe the clinical findings and gastrointestinal features of these children.

Patients and methods

12 children, consecutively referred to the department of paediatric gastroenterology with a history of a pervasive developmental disorder with loss of acquired skills and neurological symptoms (diarrhoea, abdominal pain, bloating and food intolerance), were investigated. All children were admitted to the ward for 1 week, accompanied by their parents.

Clinical investigations

We took histories, including details of immunisations and exposure to infectious diseases, and assessed the children. In 11 cases the history was obtained by the senior clinician (JW-S). Neurological and psychiatric assessments were done by consultant staff (PH, MB) with HMS-4 criteria.[7] Developmental histories included a review of prospective developmental records from parents, health visitors, and general practitioners. Four children did not undergo psychiatric assessment in hospital, all had been assessed professionally elsewhere, so these assessments were used as the basis for their behavioural diagnosis.

After bowel preparation, ileocolonoscopy was performed by SHM or MAT under sedation with midazolam and pethidine. Paired frozen and formalin-fixed mucosal biopsy samples were taken from the terminal ileum, ascending, transverse, descending, and sigmoid colons, and from the rectum. The procedure was recorded by video or still images, and were compared with images of the previous seven consecutive paediatric colonoscopies (four normal colonoscopies and three in children with ulcerative colitis), in which the physician reported normal appearances in the terminal ileum. Barium follow-through radiography was possible in some cases.

After sedation, cerebral magnetic-resonance imaging (MRI), electroencephalography (EEG) including visual, brain stem auditory, and sensory evoked potentials (where compliance made these possible), and lumbar punctures were done.

Laboratory investigations

Thyroid function, serum long-chain fatty acids, and cerebrospinal-fluid lactate were measured to exclude known causes of childhood neurodegenerative disease. Urinary methylmalonic acid was measured in random urine samples from eight of the 12 children and 14 age-matched and sex-matched normal controls, by a modification of a technique described previously.[8] Chromatograms were scanned digitally via computer, to analyse the methylmalonic-acid ratios from cases and controls. Urinary methylmalonic-acid concentrations in patients and controls were compared by a two-sample *t* test. Urinary creatinine was estimated by routine spectrophotometric assay.

Children were screened for antiendomysial antibodies and bone were screened for fragile-X if this had not been done

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Authored by Andrew Wakefield and 12 others, the paper's scientific limitations were clear when it appeared in 1998.**2 3** As the ensuing vaccine scare took off, critics quickly pointed out that the paper was a small case series with no controls, linked three common conditions, and relied on parental recall and beliefs.**4** Over the following decade, epidemiological studies consistently found no evidence of a link between the MMR vaccine and autism.**5 6 7 8** By the time the paper was finally retracted 12 years later,**9** after forensic dissection at the General Medical Council's (GMC) longest ever fitness to practise hearing,**10** few people could deny that it was fatally flawed both scientifically and ethically. But it has taken the diligent scepticism of one man, standing outside medicine and science, to show that the paper was in fact an elaborate fraud.

In a series of articles starting this week, and seven years after first looking into the MMR scare, journalist Brian Deer now shows the extent of Wakefield's fraud and how it was perpetrated (doi:10.1136/bmj.c5347). Drawing on interviews, documents, and data made public at the GMC hearings, Deer shows how Wakefield altered numerous facts about the patients' medical histories in order to support his claim to have identified a new syndrome; how his institution, the Royal Free Hospital and Medical School in London, supported him as he sought to exploit the ensuing MMR scare for financial gain; and how key players failed to investigate thoroughly in the public interest when Deer first raised his concerns.**11**

Deer published his first investigation into Wakefield's paper in 2004.**12** This uncovered the possibility of research fraud, unethical treatment of children, and Wakefield's conflict of interest through his involvement with a lawsuit against manufacturers of the MMR vaccine. Building on these findings, the GMC launched its own proceedings that focused on whether the research was ethical. But while the disciplinary panel was examining the children's medical records in public, Deer compared them with what was published in the *Lancet*. His focus was now on whether the research was true.

The Office of Research Integrity in the United States defines fraud as fabrication, falsification, or plagiarism.**13** Deer unearthed clear evidence of falsification. He found that not one of the 12 cases reported in the 1998 *Lancet* paper was free of misrepresentation or undisclosed alteration, and that in no single case could the medical records be fully reconciled with the descriptions, diagnoses, or histories published in the journal.

Who perpetrated this fraud? There is no doubt that it was Wakefield. Is it possible that he was wrong, but not dishonest: that he was so incompetent that he was unable to fairly describe the project, or to report even one of the 12 children's cases accurately? No. A great deal of thought and effort must have gone into drafting the paper to achieve the results he wanted: the discrepancies all led in one direction; misreporting was gross. Moreover, although the scale of the GMC's 217 day hearing precluded additional charges focused directly on the fraud, the panel found him guilty of dishonesty concerning the study's admissions criteria, its funding by the Legal Aid Board, and his statements about it afterwards.**14**

Furthermore, Wakefield has been given ample opportunity either to replicate the paper's findings, or to say he was mistaken. He has declined to do either. He refused to join 10 of his coauthors in retracting the paper's interpretation in 2004,**15** and has repeatedly denied doing anything wrong at all. Instead, although now disgraced and stripped of his clinical and academic credentials, he continues to push his views.**16**

Meanwhile the damage to public health continues, fuelled by unbalanced media reporting and an ineffective response from government, researchers, journals, and the medical profession.**17 18** Although vaccination rates in the United Kingdom have recovered slightly from their 80% low in 2003-4,**19** they are still below the 95% level recommended by the World Health Organization to ensure herd immunity. In 2008, for the first time in 14 years, measles was declared endemic in England and Wales.**20** Hundreds of thousands of children in the UK are currently unprotected as a result of the scare, and the battle to restore parents' trust in the vaccine is ongoing.

Any effect of the scare on the incidence of mumps remains in question. In epidemics in the UK, the US, and the Netherlands, peak prevalence was in 18-24 year olds, of whom 70-88% had been immunised with at least one

dose of the MMR vaccine.**21 22** Any consequence of a fall in uptake after 1998 may not become apparent until the cohorts of children affected reach adolescence. One clue comes from an outbreak in a school in Essen, Germany, attended by children whose parents were opposed to vaccinations. Of the 71 children infected with mumps, 68 had not been immunised.**23**

But perhaps as important as the scare's effect on infectious disease is the energy, emotion, and money that have been diverted away from efforts to understand the real causes of autism and how to help children and families who live with it.**24**

There are hard lessons for many in this highly damaging saga. Firstly, for the coauthors. The GMC panel was clear that it was Wakefield alone who wrote the final version of the paper. His coauthors seem to have been unaware of what he was doing under the cover of their names and reputations. As the GMC panel heard, they did not even know which child was which in the paper's patient anonymised text and tables. However, this does not absolve them. Although only two (John Walker-Smith and Simon Murch) were charged by the GMC, and only one, the paper's senior author Walker-Smith, was found guilty of misconduct, they all failed in their duties as authors. The satisfaction of adding to one's CV must never detract from the responsibility to ensure that one has been neither party to nor duped by a fraud. This means that coauthors will have to check the source data of studies more thoroughly than many do at present—or alternatively describe in a contributor's statement precisely which bits of the source data they take responsibility for.

Secondly, research ethics committees should not only scrutinise proposals but have systems to check that what is done is what was permitted (with an audit trail for any changes) and work to a governance procedure that can impose sanctions where an eventual publication proves this was not the case. Finally, there are lessons for the Royal Free Hospital, the *Lancet*, and the wider scientific community. These will be considered in forthcoming articles.

What of Wakefield's other publications? In light of this new information their veracity must be questioned. Past experience tells us that research misconduct is rarely isolated behaviour.**25** Over the years, the *BMJ* and its sister journals *Gut* and *Archives of Disease in Childhood* have published a number of articles, including letters and abstracts, by Wakefield and colleagues. We have written to the vice provost of UCL, John Tooke, who now has responsibility for Wakefield's former institution, to ask for an investigation into all of his work to decide whether any more papers should be retracted.

The *Lancet* paper has of course been retracted, but for far narrower misconduct than is now apparent. The retraction statement cites the GMC's findings that the patients were not consecutively referred and the study did not have ethical approval, leaving the door open for those who want to continue to believe that the science, flawed though it always was, still stands. We hope that declaring the paper a fraud will close that door for good.

Notes

Cite this as: *BMJ* 2011;342:c7452

Footnotes

- Feature, doi:10.1136/bmj.c5347
- Competing interests: All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years. HM chairs GMC fitness to practise panels. He had no association with the Wakefield hearings and the views expressed in this article are his own and do not represent those of the GMC.

- Provenance and peer review: Commissioned; not externally peer reviewed.

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Intended for healthcare professionals

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Corrections

Wakefield’s article linking MMR vaccine and autism was fraudulent

BMJ 2011; 342 doi: https://doi.org/10.1136/bmj.d1678 (Published 15 March 2011) Cite this as: BMJ 2011;342:d1678

The *BMJ* should have declared competing interests in relation to this editorial by Fiona Godlee and colleagues (*BMJ* 2011;342:c7452, doi:10.1136/bmj.c7452). The BMJ Group receives advertising and sponsorship revenue from vaccine manufacturers, and specifically from Merck and GSK, which both manufacture MMR vaccines. For further information see the rapid response from Godlee (http://www.bmj.com/rapid-response/2011/11/03/response-john-stone). The same omission also affected two related Editor’s Choice articles (*BMJ* 2011;342:d22 and *BMJ* 2011;342:d378).

Notes

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First-Tier Tribunal
(General Regulatory Chamber)
Information Rights **Appeal reference: EA.2022.0039**

BETWEEN:

Marco Tullio Suadoni

Appellant

-and-

Information Commissioner

First Respondent

and-

Medicines and Healthcare products Regulatory Agency

Second Respondent

OPEN WITNESS STATEMENT OF DAME JUNE RAINE, DBE

I, June Raine of the Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, London E14 4PU, **WILL SAY AS FOLLOWS**

Introduction

1. I am Chief Executive of the Medicines and Healthcare products Regulatory Agency ("**MHRA**").

2. The facts and matters contained in this witness statement are either within my own knowledge and are true or are based on the sources identified below and are true to the best of my knowledge and belief.

3. I have been shown a bundle of documents which are exhibited to this witness statement. Those exhibits are indicated by "**JRx**".

4. This statement should be read in conjunction with the MHRA's Response to Appeal, dated 18 May 2022. I do not repeat here the details contained therein.

5. In this statement I will address the following:

(1) overview of the MHRA;
(2) overview of the MHRA's safety monitoring of COVID-19 vaccines;
(3) the distinction between the data the MHRA is currently publishing and that which is requested;
(4) the MHRA's ongoing upgrade to its safety reporting systems; and
(5) the risks of publishing the requested data before the new system is live.

Overview of the MHRA

6. The MHRA has a statutory responsibility to monitor the safety of medicines and vaccines which it has authorised, including COVID-19 vaccines.

7. One of the MHRA's main roles therefore is to continually monitor the safety of medicines and vaccines during widespread use, and we have in place a proactive strategy to do this for COVID-19 vaccines.

8. All vaccines and medicines have some side effects and so these side effects need to be continuously balanced against the expected benefits in preventing illness. As with the development of any new vaccine or medicine, the size of clinical trials means that very rare side effects can only be identified and/or fully characterised when the products are used in large populations. The MHRA, along with the Marketing Authorisation Holder[1] for the product, therefore, monitors the effectiveness and safety of all medicinal products including COVID-19 vaccines on an ongoing basis to ensure their benefits continue to outweigh any risks for patients and the public health.

9. The MHRA undertakes the collection of data on suspected adverse reactions for medical products via the Yellow Card scheme, along with rigorous scientific

[1] A Marketing Authorisation Holder (MAH) is a company or organisation that has been granted a marketing authorisation. The marketing authorisation allows the holder to market a specific medicinal product.

assessment of available evidence on quality, safety and efficacy and communication of information to support the safe and effective use of medicinal products.

Overview of the MHRA's safety monitoring of COVID-19 vaccines

10. Ahead of COVID-19 vaccine deployment in the UK, the MHRA developed, with advice from the Expert Working Group on COVID-19 vaccine safety surveillance, a proactive strategy for conducting COVID-19 vaccine safety surveillance. This proactive approach to vigilance aims to make best use of data sources, both UK and international, and available technologies for data management. This COVID-19 Vaccine Safety Surveillance Strategy was published on 5 February 2021.[2] I exhibit at copy at **JR1**.

11. This COVID-19 Vaccine Safety Surveillance Strategy supports the rapid detection, confirmation, characterisation and quantification of any new risks not detected in clinical trials. A signal of a potential safety concern may come from a range of sources. This would include pre-licensure clinical trials, Yellow Card (see further paragraph 13 below) reports of suspected adverse reactions from patients and healthcare providers, and post-authorisation epidemiological studies. A signal can also arise from UK or international data. The COVID-19 Vaccine Safety Surveillance Strategy also supports further investigation to consider whether events which appear to be temporally related to vaccination are coincidental or whether there is a causal association based on the available evidence, biological plausibility and through the application of formal epidemiological studies. The COVID-19 Vaccine Safety Surveillance Strategy explains how the MHRA makes optimal use of UK data both directly accessible to the MHRA and across other Public Health Bodies and the NHS. Additionally, the MHRA has taken a leading role in the International Coalition of Medicines Regulatory Authorities' Vaccines Pharmacovigilance Network and has used international bilateral agreements to exchange information with other regulatory authorities before and after vaccine authorisation.

12. All data on vaccine safety arising from the approaches described in the COVID-19 Safety Surveillance Strategy, as well as further relevant data on safety from elsewhere along with data on vaccine effectiveness and exposure are fed into continuous

[2] Available at: https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance

evaluation by the MHRA of the balance of benefits of each vaccine versus the risks. The MHRA regularly seeks advice from the Commission on Human Medicine (CHM)and its Expert Advisory and Working Groups, particularly the COVID-19 Vaccines Benefit Risk Expert Working Group ("**VBR EWG**") on the strength and interpretation of the evidence to inform regulatory action to minimise risk and support safe use, and to inform any extension of the authorisation of the vaccines to new patient populations including new age groups of recipients. Relevant safety evidence and any actions taken based upon it are also communicated to the Department of Health and Social Care, devolved Governments, and public health agencies to inform their decisions regarding the immunisation programme as well as to the public.

13. The MHRA monitors the safety of COVID-19 vaccines via a number of activities. One of these activities is through the Yellow Card scheme. This is a mechanism by which any member of the public or healthcare professional can submit reports of suspected side effects associated with a medicine or vaccine.[3] The scheme collects and monitors information on suspected safety concerns involving vaccines, medicines, medical devices, blood products, defective medicines and e-cigarettes. The scheme relies on voluntary reporting of suspected adverse reactions and the purpose of the scheme is to provide an early warning that the safety of a product may require further investigation.

14. It is important to note that a Yellow Card report does not necessarily mean that a medicine or a vaccine caused that reaction or event. The MHRA asks for any suspected side effects to be reported, even if the reporter is not sure if it was caused by the medicine or vaccine. Reports to the scheme are known as suspected adverse drug reactions ("**ADRs**").

15. Many suspected ADRs reported through the Yellow Card Scheme do not have any causal relation to the vaccine or medicine and it is often coincidental that symptoms or events occurred around the same time as vaccination or use of medication. The reports are continually reviewed to detect possible new or changing side effects that may require regulatory action and to differentiate these from events that would have occurred regardless of the vaccine or medicine being administered, for instance due to underlying or undiagnosed illness.

[3] This is accessible at: https://yellowcard.mhra.gov.uk/

16. Whilst Yellow Card reports are sufficient to support signal detection[4], the MHRA enhances signal detection via continuous evaluation of the 'observed' number of reports of a suspected serious side effect for COVID-19 vaccines compared to 'expected' numbers of events – i.e. based on the naturally-occurring rate of events that would normally happen in a given time period in the same sized age cohort and in the absence of vaccination. The background rate of the event of interest in the absence of vaccination is obtained from the Clinical Practice Research Datalink ("**CPRD**") and other datasets. Such observed vs expected analysis determines whether more events are occurring after the vaccine than we might expect by coincidence, and therefore whether it could signal a possible vaccine-related side effect. This vigilance approach is well-established within the MHRA for new vaccines.

17. Further, the MHRA routinely monitors published and unpublished data from epidemiological studies such as cohort studies and self-controlled case series exploring the safety of COVID-19 vaccines and conducted using data sets such as the CPRD, national hospital data including Hospital Episode Statistics and similar international sources as well as monitoring effectiveness studies.

18. The MHRA enhances the robustness of the surveillance system for COVID-19 vaccines by analysing reports in the context of near real-time information on vaccine usage i.e. the number of doses of vaccine administered at the relevant time point, stratified by age and sex.

19. The MHRA publishes a weekly public summary of Yellow Card reporting in relation to COVID-19 vaccines.[5] This provides an overview of all UK suspected ADRs of Special Interest associated with the COVID-19 vaccines and the MHRA's analysis of the data. Information on new and emerging safety concerns is provided in this report together with details of any resulting regulatory action or changes to advice on use of the vaccines. A list of the possible side effects for deployed vaccines is provided in the

[4] Signal detection is the process by which data is used to determine whether there is a possible new or changing causal association between an adverse event and a medicinal product, which was previously unknown or incompletely documented.
[5] Available at: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

product information document for healthcare professionals and the UK recipient information. These can also be found on the Coronavirus Yellow Card reporting site.[6].

The distinction between the data the MHRA is currently publishing and that which is requested

The data MHRA currently publishes

20. Currently, the MHRA publishes data on COVID-19 vaccines weekly in a largely narrative form which provides both a detailed narrative assessment of the data received from Yellow Card as well as that data in a static PDF format.

21. The narrative assessment[7] of the data received from Yellow Card and that available from other sources contains information on safety in specific populations and comments on specific safety topics. Where helpful for interpretation, these sections provide a break-down of reports received in different geographic regions, age groups or sexes. These narrative assessments are independently reviewed by the CHM[8] and its COVID-19 Vaccine Benefit Risk Expert Working Group. I exhibit an example at **JR2** dated 26 May 2022.

22. Alongside the publication of the narrative summary of the MHRA's assessments, the MHRA also publishes weekly Vaccine Analysis Prints[9]. The Vaccine Analysis Prints contain a complete listing of all suspected adverse reactions that have been reported to the MHRA for each COVID-19 vaccine at an aggregated level. They contain detail on how many times each suspected adverse reaction was reported as well as the number of those reactions that were reported alongside a fatal outcome. I exhibit an example at **JR3** of the vaccine analysis print for the Pfizer/BioNTech COVID-19 vaccine for the period 9/12/20 to 18/05/22.

23. The Yellow Card scheme relies on voluntary reporting of suspected adverse reactions by healthcare professionals and members of the public (patients, users, or carers). The scheme has been widely publicised on healthcare professional training materials and patient-facing materials produced by marketing authorisation holders, the UK

[6] As per the above at: Product Information | Coronavirus (COVID-19) (mhra.gov.uk)

[7] Available at: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

[8] Available at: https://www.gov.uk/government/organisations/commission-on-human-medicines

[9] Available at: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting#annex-1-vaccine-analysis-print

Health Security Agency and Devolved Administrations. The MHRA has seen an increased level of reporting of suspected adverse reactions as a result of this as well as other factors such as patient reports driven by the media.

The data requested

24. Mr Suadoni has requested the data in interactive Drug Analysis Profile ("**iDAP**") format. This data format is an interactive format used by the MHRA for publication of data on drugs[10]. This format was not designed for and has not to date been used for publication of data in relation to vaccines. The Appellant argues that review and analysis of the vaccination data outside of the MHRA, and by means other than the MHRA algorithm, are said to provide an additional measure of public security. However, iDAP data releases do not support data for research purposes as more detailed data would be needed. The MHRA accepts applications for scientific data for research purposes which would require a submission of a scientific protocol to the CHM's Pharmacovigilance Expert Advisory Group. iDAP data (and the current ADR reporting) is made available purely for transparency purposes. In any event, it is clear that this data will be released. However, the MHRA maintains that the risks associated with the publication of raw data without proper context and explanation are serious and justify publication in accordance with the timeline it has set.

25. Each iDAP contains anonymised data for all spontaneous side effects (ADRs), reported for that drug substance. This format enables the user to filter the data to focus on information in particular areas of interest. For example, users can filter by patient age group, patient sex, the year the report was received, who reported the adverse event (patient, healthcare professional or industry), route of product administration and seriousness (fatal, serious or non-serious reports). It also allows the user to filter based on System Organ Class, which is the highest level of the Medical Dictionary for Regulatory Activities (MedDRA) hierarchy. As identified above, this format was not designed for and has not to date been used for publication of data in relation to vaccines but the information is held and could be produced in this format. However, I have very real concerns with providing this information as held, rather than through the MHRA's systems, and to the MHRA's timeline, for the reasons highlighted throughout this statement.

[10] Available at: https://yellowcard.mhra.gov.uk/idaps

The MHRA's ongoing upgrade to its safety reporting systems

The upgrade programme

26. The MHRA is undertaking a major investment programme to upgrade its safety reporting systems. The SafetyConnect programme is using new technology to improve its responsiveness to patients and a new modern vigilance database using artificial intelligence will support the more rapid identification of safety signals across medicines, medical devices and blood products and product quality defects. Throughout the development of the new system, the MHRA has engaged with patients and the public directly to gain user feedback and perceptions on the system via user needs sessions.

27. The work is now at an advanced stage of testing prior to full implementation and the SafetyConnect programme team will continue to enhance the service over the coming months. A new Yellow Card website[11] went live in February 2022, building on the improvements made to the Coronavirus Yellow Card site that was deployed in May 2020 and enhanced throughout the pandemic. Other recent enhancements include installing new functionality that enables patients to update their own reports and for the MHRA to raise requests for additional information from reporters to aid the ongoing assessment of their reports. These changes have enabled integration of Yellow Card into other services such as the NHS App and will make the Yellow Card scheme more informative with new information presented to users by the end of 2022.

Benefits of the new system

28. The SafetyConnect programme will enable us to develop vaccine specific presentations of the data, building on what is available within the current iDAP format for drugs but with context relevant information for vaccines which will aid user interpretation of the data and help avoid misinterpretation.

29. The new data presentation format is intended to enable the volumes of ADRs reported with vaccines to be contextualised with the usage of the product, giving the user an understanding as to why the volumes of reports have increased and decreased at different stages, in line with usage of the products and increasing understanding of the

[11] https://yellowcard.mhra.gov.uk/

frequency of reporting of a suspected adverse drug reaction. For example, with new products it is expected that reporting particularly of non-serious side effects will be higher in the early stages of use, decreasing as patients better understand what to expect from their own experiences. This is the type of contextualised information which will be provided alongside the iDAPs.

30. In delivering this new format we must be mindful of the need to protect the confidentiality of information submitted related to individuals and prevent re-identification. This is particularly relevant in the context of the COVID-19 vaccination programme, given the unprecedented level of information in the public domain in both the mainstream media and social media which could potentially enable identification of individuals in small data sets, for example. The new format will also offer additional protection to individuals, preventing the data being filtered to such an extent that could risk identification or re-identification of individuals.

31. Under the new Safety Connect System we will add further rigour to our already robust approach to identifiability. The new tools which are under development will enable automatic aggregation or anonymisation where numbers of reports are fewer than 5, to prevent potential for over filtering of the data leading to risk to identification. This will enable the Agency to make additional data fields available (such as ethnicity), but in such a way that does not risk identification of individuals. These safeguards are particularly important in the context of rare side effects of vaccines that have been widely published in mainstream and social media and our obligations under GDPR to prevent re-identification of individuals.

Risks of publishing the requested data before the new system is live

The key risks and difficulties of releasing the data as requested and before the new system is live, are as follows:

Difficulty releasing the data in the requested format

32. While it is technically possible to push vaccine data into the existing iDAP format, this is not a configuration that was designed for presentation of vaccine data. When the MHRA began preparation of the vaccine data into this format, a significant number of concerns were raised about the potential for misinterpretation of the data. The format

also does not meet required accessibility standards[12] and will be replaced in the near future through a major investment programme, which is described above.

33. As such there are substantial risks in publishing the data in the iDAP format, including;

i) potential for misinterpretation
ii) potential for use in misinformation campaigns
iii) potential to increase vaccine hesitancy

34. We consider that these could be better mitigated by provision of supplementary information on interpretation and use, because we know that such guidance and caveats are frequently ignored, as can be seen in recent judgements by the advertising standards authority (see paragraph 41 below). Nevertheless, any such guidance would require discussion with the CHM and its COVID-19 Vaccine Benefit Risk Expert Working Group and improvement in an iterative approach.

35. Whilst only limited technical work would be required to release iDAPs in the existing format (as has been outlined above, substantial risks exist in publishing the data in that format. This is because the data would be published "raw", i.e. without accompanying communications materials to explain, and mitigate, the risks around misinterpreting data.

36. Further, delivery of the iDAPs publicly is currently timed to occur only after SafetyConnect is deployed. SafetyConnect is a complex information technology programme to replace the full MHRA surveillance system (in line with the above), and replacement of iDAPs are a part of that programme which is entirely dependent on delivery of the remainder of the programme to function. SafetyConnect is not about producing a video or guidance sheet, but enhancing the whole surveillance system in line with the Independent Medicines and Medical Devices Safety Review report recommendations.

37. We have adopted this timeline for two key reasons. Firstly, it enables us to deploy the vaccine data, where there are risks around misinformation, in a format which better protects against those risks. Secondly, it conserves resources, insofar as we do not

[12] This means that the website format does not meet the criteria needed to fully assist people who may have impairments to their sight, hearing, movement, memory or thinking to access the content.

have to prepare the data for publication in two separate formats, in relatively quick succession. I would also note that to publish the data in two different formats also risks stakeholder confusion resulting from the different formats.

Potential for misinterpretation

38. There are particular concerns around the impact of misinformation and confusion about COVID-19 vaccines, given both the sensitivity around the vaccines and their key role in managing the COVID-19 pandemic.

39. These concerns will not be new to the Tribunal. However, there are specific examples I can provide to the Tribunal which demonstrate the extent of the risk of misinformation about vaccines being promoted publicly.

40. Following release by the FDA of a regulatory report produced by Pfizer summarising post marketing safety data concerning the Pfizer/BioNTech COVID-19 vaccine up to 28 February 2021 (which contains the usual caveats but is presented for Regulatory review and not public consumption) there has been widespread misinterpretation by the public of the data. In particular, the numbers of suspected adverse events and deaths reported have been frequently been misinterpreted; specifically, a large number of enquiries have been made to MHRA based on an assumption that any event mentioned in the report is confirmed a side effect and that this represents clinical trial data (and not spontaneous reports by members of the public). I exhibit a copy of the regulatory report at **JR4**.

41. Misinformation has also been linked to the Yellow Cards specifically. There has been misreporting around purported vaccine deaths and miscarriage rates in pregnancy. See for example the registered Charity "Full Fact" articles "*Miscarriage does not occur in 90% of vaccinated pregnant women*" and "*Vaccine deaths are not higher than Covid-19 deaths'* (see Exhibits **JR5** and **JR6** attached to this statement).

42. We are also aware of Rulings which the Advertising Standards Authority (ASA) have issued whereby Yellow Card data, or references to the Coronavirus Yellow Card website had been misleadingly used (see for example, Exhibits **JR7** and **JR8** attached to this statement). This demonstrates the risk that individuals will intentionally or otherwise use the Yellow Card website and the published data to produce and

publicise their own narrative about vaccine safety, using Yellow Card references and similar branding to suggest their narrative has our endorsement. We have an established regular publication of safety data which will be replaced by our new longer-term process upon completion of the SafetyConnect work (paragraphs 26-31).

43. We consider that that disclosing the requested iDAP data as it stands now (before the completion of the SafetyConnect work) has the potential to cause confusion by in effect changing our publication process twice in a relatively short space of time, necessitating two sets of communication materials, whilst not overcoming any of the disadvantages as set out earlier in this statement. There is the potential that those who have intentionally or otherwise misused this data previously will do so again and will refer to three publication types in a short timeframe to create their own narrative around the data.

Potential for vaccine hesitancy

44. Vaccines have always had increased sensitivity around their use, and the individual benefits and risks for those who use them, which results in vaccine 'hesitancy'. This is because a vaccine is given to someone who is healthy (in terms of target disease) and may never be exposed to the disease and associated risks from that disease. The benefit for these individuals is an indirect or delayed one, as they are not currently suffering from the disease. COVID-19 therapeutics on the other hand are only offered to people in high-risk groups which have already been infected with COVID-19 (i.e. there is a tangible risk of adverse outcome). We have therefore taken a different approach for vaccines compared with therapeutics because of the different risks to health from misinformation.

45. The Tribunal will be aware that there has been a very real issue in relation to people being hesitant to take a COVID-19 vaccine and then, unfortunately becoming very ill from the virus, for example during pregnancy.

46. There is clear and compelling evidence that public misinformation can impact a vaccination campaign. As referenced in the MHRA's Response to Appeal, dated 18 May 2022, fraudulent data led to a fear over a false association between MMR vaccination rates and health consequences which led to a significant reduction in MMR

vaccination rates in the UK. I exhibit a British Medical Journal article regarding MMR vaccination at **JR9**.

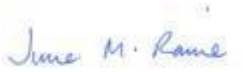
47. A further real-life example outside of COVID-19 was the decision to stop the Japanese HPV vaccination campaign as referenced in the MHRA's Response to Appeal, dated 18 May 2022. This followed misinterpretation of published data, which has the potential to result in a significant number of deaths from cervical cancer which would otherwise have been prevented.

48. Without the enhancements described above which are being implemented through the SafetyConnect programme, there is a significant risk that the data sought to be released would be misinterpreted by a minority of individuals. Even if the data is only misinterpreted by a minority of individuals, this has the potential to result in a significantly increased rate of vaccine hesitancy and, it follows, adverse public health outcomes.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings for contempt of court may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.

Signed:



Dame June Raine, DBE
Chief Executive of the Medicines and Healthcare products Regulatory Agency

Dated 31 May 2022

First-Tier Tribunal
(General Regulatory Chamber)
Information Rights **Appeal reference: EA.2022.0039**

BETWEEN:

Marco Tullio Suadoni

Appellant

-and-

Information Commissioner

First Respondent

and-

Medicines and Healthcare products Regulatory Agency

Second Respondent

EXHIBITS JR1-9

These are the documents marked Exhibits JR1-9 to the witness statement of Dame June Raine, DBE

First-Tier Tribunal

(General Regulatory Chamber)

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EXHIBITS JR1-9

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Item	Document	Date	Page Number
JR1	Report of the Commission on Human Medicines Expert Working Group on COVID-19 vaccine safety surveillance	5 February 2021	1-9
JR2	Coronavirus Vaccines Summary of Yellow Card reporting	26 May 2022	10-50
JR3	COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print	20 May 2022	51-168
JR4	Pfizer Cumulative Analysis of Post-authorization Adverse Event Reports	April 2021	169-206
JR5	Full Fact - Miscarriage does not occur in 90% of vaccinated pregnant women	23 November 2021	207-208
JR6	Full Fact - Vaccine deaths are not higher than Covid-19 deaths	6 August 2021	209-210
JR7	ASA Ruling on Stacey Bradley	25 May 2022	211-215
JR8	ASA Ruling on Steven Thomas	2 February 2022	216-219
JR9	Wakefield's article linking MMR vaccine and autism was fraudulent	6 January 2011	220-223

Research and analysis

Report of the Commission on Human Medicines Expert Working Group on COVID-19 vaccine safety surveillance

Published 5 February 2021

Contents

This publication is available at https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance

Summary

In May 2020, the Commission on Human Medicines established an Expert Working Group (EWG) to advise the Medicines and Healthcare products Regulatory Agency (MHRA) on its safety monitoring strategy for COVID-19 vaccine(s).

The EWG held four meetings from May to October 2020, during which it considered proposals and methodologies for MHRA-led vigilance activities. Based on this advice, the MHRA has developed, and now has in place, a four-stranded approach to vigilance, which is summarised in this report

Background

Since the emergence of the COVID-19 pandemic, research and development of candidate vaccines to protect against the SARS-CoV-2 virus has gathered pace at global level. In the UK, a Government Vaccine Task Force (VTF) has been established to expedite and co-ordinate efforts to research, produce and supply a COVID 19 vaccine (https://www.gov.uk/government/news/government-launches-vaccine-taskforce-to-combat-coronavirus).

Several vaccines have now been authorised for use, and many more are at an advanced stage of development, at global level (https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines). These are based on a range of technology, some of which is very well-established in other authorised vaccines (such as inactivated virus or purified protein subunits, with or without an adjuvant), some are based on viral vector platforms, including those used in recently-authorised vaccines (such as Ebola vaccine) and others are based on emerging mRNA technology.

In the UK, as of 14 January 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) has authorised the supply of the Pfizer/BioNTech (https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19), the Oxford University/AstraZeneca (https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca) and Moderna (https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna) vaccines, following a thorough review of the safety, quality and efficacy. These are now being deployed in the UK in accordance with the recommendations of the UK Joint Committee on Vaccination and Immunisation (JCVI).

The need for post-authorisation vigilance

The intense focus, rapid funding, recruitment and prioritised regulatory oversight of trials at global level has allowed clinical trials for COVID-19 vaccines to proceed at pace, without compromising any of the usual, high standards of scientific rigour. In accordance with the usual requirements to support an authorisation of a new vaccine, tens of thousands of subjects have been included in trials and all are subject to very close safety follow-up over several months.

As with the development of any new vaccine or medicine, the size of clinical trials invariably means that very rare side effects can only be identified and/or fully characterised when the products are used in large populations. And certain groups who may benefit from, and be recommended to receive a vaccine, such as those with underlying chronic illnesses, may have been excluded from clinical trials.

It is for these reasons that post-authorisation, 'real world' safety vigilance of new vaccines and medicines is a crucial part of the product lifecycle and the public health programme. As well as authorising the use of new vaccines and medicines, the MHRA has statutory responsibility for undertaking post-authorisation safety monitoring in the UK. The MHRA also oversees the manufacturers' legal responsibilities to undertake such vigilance.

Independent expert oversight of the MHRA's activities

To inform its decision-making, the MHRA seeks independent expert advice from the Commission on Human Medicines (CHM). In May 2020, the CHM established an Expert Working Group (EWG), consisting of experts in medicine, infectious disease, pharmacoepidemiology and data analytics to provide the MHRA with independent oversight and advice on its COVID-19 vaccine vigilance activities.

The EWG held four meetings from May to October 2020, during which it considered proposals and methodologies for MHRA-led vigilance activities. Based on this advice, the MHRA has developed, and now has in place, a four-stranded approach to vigilance. To ensure the necessary communications, data flows and linkages are in place to fulfil these activities, the MHRA has worked in close collaboration with public health partners across the UK, including Public Heath England (PHE), the respective public health authorities in Scotland, Wales and Northern Ireland, as well as the Department for Health and Social Care (DHSC), NHSEI, NHSD and NHSX. The MHRA has also incorporated scientific collaboration with the NIHR-funded Health Protection Research Unit, within the London School of Hygiene and Tropical Medicine.

This collaborative approach harnesses collective expertise across the UK public health sector, and to make best use of the data sources and methodologies available, to implement a robust vigilance strategy.

This report summarises the activities that the MHRA will have in place for proactive vigilance of COVID-19 vaccines. Although this focuses on the post-marketing safety of the vaccines, the 'real world' effectiveness and population impact of the vaccine(s) are key to overall continuing benefit-risk balance and will include longevity of protection, any need for boosters and evaluation of other vaccine characteristics such as prevention of viral transmission.

Public Health England published its COVID-19 vaccine surveillance strategy (https://www.gov.uk/government/publications/covid-19-vaccine-surveillance-strategy) on 11 January 2020 setting out how it will independently monitor these other important aspects of COVID-19 vaccines following their roll-out. This will be in accordance with the clinical recommendations of the JCVI.

Proactive vigilance for COVID-19 vaccines

Identifying side effects, and distinguishing these from coincidental medical events

Given the likely scale of a COVID-19 mass immunisation programme, with many millions of doses of one or more novel vaccines administered across the UK over a relatively short time period, vigilance needs to be continuous, proactive and as near real-time as is possible. The importance of this is two-fold.

First and foremost to rapidly detect, confirm, characterise and quantify any new risks that were not detected in clinical trials, to weigh these against the expected benefits and take any necessary action to minimise risks to individuals.

Secondly, it needs to be very quickly established if any serious events which are temporally-related to vaccination are merely a coincidental association, and to do this in a robust, evidence-based way so that public confidence in a vaccine is not eroded unnecessarily. Indeed, such associations may be more likely whilst we are still in the midst of a national epidemic, and because most of the millions of people offered the vaccine in the early phase of a vaccination campaign will be elderly and/or have underlying medical conditions, which increases the likelihood of unrelated illnesses occurring soon after vaccination.

Four main strands of our proactive vigilance

There are four strands to the MHRA's strategy, which combine to address the relative strengths and weaknesses of each form of vigilance.

1. Enhanced passive surveillance – 'observed vs expected' analysis

The Yellow Card scheme underpins medicines and vaccines safety monitoring in the UK. Through this scheme, members of the public and healthcare professionals voluntarily submit reports of suspected side effects to the MHRA. Drug companies also submit such reports as part of their legal requirements. Safety scientists at the MHRA continuously evaluate Yellow Card reports to generate "signals" of potential safety issues. It is important to point out that just because a Yellow Card has been submitted, it does not necessarily mean that the vaccine caused the reaction – as outlined above, it may be also coincidental. The MHRA encourages anyone to report any suspicion or concern they have – reporters do not need to be sure of a link between a medicine or vaccine and a suspected side effect, and encouraged to report if in doubt. Every report is taken seriously, and we may get in contact reporters to obtain further information.

The MHRA has developed a dedicated COVID-19 interface to the Yellow Card scheme (https://coronavirus-yellowcard.mhra.gov.uk/) focused on the capture of suspected side effect reports for COVID-19 products, which will be expanded to include vaccines.

Our standard Yellow Card site (https://yellowcard.mhra.gov.uk/), and mobile apps can also be used to report to us. Although paper-based Yellow Card reports are still accepted, the pandemic situation may delay access to such reports and on-line reporting is strongly recommended.

As with any system of safety vigilance, the ability to very rapidly detect a new safety concern in the midst of a mass immunisation campaign is dependent on the early presentation and diagnosis of symptoms. The key strength of the Yellow Card scheme is that it allows any member of the public or health professional across the UK to immediately alert us to any concerns they have without a formal diagnosis. And because anyone across the UK can report to the MHRA at any time, unlike studies which are limited in size, the scheme is able to identify the rarest of side effects.

A team of MHRA scientists will continually review individual reports and will contact reporters to obtain more information, where required. Scientific and clinical assessment will be used to determine if an individual or series of reports indicate a new safety 'signal'. An established statistical approach known as empirical Bayes geometric mean (EBGM) (http://www.encepp.eu/standards_and_guidances/methodologicalGuide9.shtml) will be used to facilitate signal detection.

Whilst Yellow Cards in isolation are sufficient to allow signal detection, the MHRA will enhance the system by analysing reports in the context of near real-time information on the number of doses of administered at the relevant time point, stratified by age and gender, and the background rate of the event of interest in the absence of vaccination. This will allow continuous evaluation of the 'observed' number of reports of a suspected serious side effect compared to 'expected' numbers – i.e. based on the naturally-occurring rate that would normally happen in a given time period in the same sized cohort and in the absence of vaccination.

The background rate used to estimate the expected numbers of cases will be extracted from anonymised GP electronic healthcare records and linked secondary care records within the Clinical Practice Research Datalink (https://www.cprd.com/) (CPRD) supported by additional analyses using full England-wide secondary care data for the rarest events. The MHRA will then continually compare the 'observed' vs 'expected' numbers to determine whether more events are occurring after the vaccine than we might expect by coincidence, and therefore whether it could signal a possible vaccine-related side effect. By applying a statistical method known as 'MaxSPRT'7 to this analysis, we reduce the chance of false signals caused by repeated interrogation of the data. This is a vigilance approach now well-established within the MHRA for major new vaccines (HPV (https://doi.org/10.1016/j.vaccine.2013.08.024) and 4CMenB (https://www.sciencedirect.com/science/article/abs/pii/S2352464218301032?via%3Dihub)).

Because every passive surveillance system suffers from variable under-reporting, the MHRA will conduct sensitivity analyses based on a range of under-reporting assumptions. Everyone receiving a vaccine should be provided with an information leaflet, which will provide a link to the Yellow Card site, and which should help to reduce any under-reporting.

2. Rapid Cycle Analysis and Ecological analysis

Any form of passive surveillance relies on someone suspecting or 'making a connection' between the medicine or vaccine and an unexplained illness, and then reporting it. It is important, therefore, that other forms of vigilance are included to supplement the Yellow Card scheme. Analysing anonymised electronic healthcare records that are routinely collected in clinical practice is one way to do this. The MHRA has access to CPRD data and routinely uses this in vaccine vigilance.

The CPRD Aurum dataset (https://www.cprd.com/article/data-resource-profile-cprd-aurum) now captures daily data from ~20% of GP practices in England, now including 13 million currently registered patients. The advantage of supplementing vigilance activities with such data is that it does not rely on people directly reporting their concerns. But, unlike passive surveillance, a limitation of using electronic healthcare records for this purpose is that it relies on the timely and accurate recording or linkage in GP IT systems of vaccinations given, as well as any referrals/diagnoses for illness. It is therefore not as real-time as Yellow Card reporting for safety signal detection.

However, as COVID-19 vaccination records (i.e. those given outside of GP surgeries) begin to get updated within GP systems, the MHRA will implement a form of active surveillance known as 'Rapid Cycle Analysis' (https://doi.org/10.1542/peds.2010-1722I). This method involves proactive, weekly analysis of a range of pre-defined events (theoretical side effects) to quickly identify safety signals – it again involves 'observed vs expected' analyses (i.e. comparing rates after vaccination to rates in unvaccinated comparator groups) but doesn't rely on people directly reporting any concerns through the Yellow Card scheme. It is also a more robust way to quickly determine if rates are likely to be consistent with a coincidental association. It also uses the MaxSPRT approach with

adjustments made for the expected delays in the recording of events presenting to and diagnosed in secondary care settings. The list of pre-defined events of special interest is not fixed and can be expanded at any time.

The MHRA will also use the CPRD data to conduct 'ecological analyses' (https://doi.org/10.1016/j.vaccine.2013.08.024). This involves monitoring trends in the rates of pre-defined events within given population cohorts, based on prioritisation groups for vaccine roll out, to see if they are occurring to a greater extent amongst those targeted for vaccination after it is deployed compared to historical rates from the pre-deployment period. Comparisons can also be made to trends seen in groups not targeted for vaccination at the same time. This approach is most useful when we see high vaccine uptake and is another way to quickly detect a potential safety signal.

Each of these methods will need very careful evaluation to tease out any change in rates over time that may be a direct or indirect consequence of the SARS-CoV-2 epidemic, rather than an effect of the vaccine.

3. Targeted active monitoring – Yellow Card Vaccine Monitor

Another form of vigilance that the MHRA will implement is targeted active monitoring of certain groups of vaccinees, focused particularly on those who may have been excluded or under-represented in clinical trials. Through the call/recall system which the NHS will use to invite people to register to receive the vaccine, a random selection of vaccinees from certain cohorts will be invited to voluntarily register for follow-up via a new platform, called the Yellow Card Vaccine Monitor, which the MHRA has developed.

This vigilance activity will seek enrolment prior to vaccination (and thereby before any suspected side effect is experienced) and vaccinees will then be contacted at set intervals (for example 7 days, 28 days, 3-6 months) to ask whether any adverse reaction occurred. The objective of this is not necessarily to detect very rare risks, as the intention is to recruit the same numbers that are generally included in a clinical trial (i.e. several thousand), but to compare the frequency and severity of side effects to groups that were included in trials to allow further characterisation of the safety profile. This would allow, for example, further evaluation of the safety profile in people with underlying immunosuppression.

4. Formal epidemiological studies

The above three methods are essentially 'signal detection' and 'signal strengthening' tools – i.e. their main purpose is to quickly flag up whether there might be a new, rare side effect and to build the volume of data on safety. They cannot confirm if it is a side effect. Similarly, whilst they can provide some strong evidence to indicate if something is likely to be coincidental, they can not always confirm this. A formal epidemiological study, designed and powered specifically to test a given hypothesis in an unbiased way, is usually necessary to confirm and quantify a suspected rare side effect. These will be undertaken on an ad hoc basis should the need arise based on other vigilance activities.

Examples of such studies undertaken by the MHRA in the past include the association between human papillomavirus (HPV) vaccine and chronic fatigue syndrome and the safety of pertussis vaccine in pregnancy (pertussis (https://doi.org/10.1136/bmj.g4219) and HPV (https://www.sciencedirect.com/science/article/pii/S0264410X13011158?via%3Dihub).

There are a number of data sources and study designs that could be utilised for generating robust evidence regarding specific risks should this be required. It is important that for any specific issue the strongest data set for further evaluating the risk is identified. This will be dependent upon the nature of the potential risk that has been identified. The

MHRA can make direct use of the CPRD data. Should the signal originate from our analyses of CPRD Aurum data mentioned above, use of alternative data bases would be preferred in the first instance (for example, through OpenSafely) although use of the CPRD Gold data set15 (which differs from CPRD Aurum in that it contains data contributed by GP practices using the Vision® rather than EMIS Web® electronic patient record system) and inclusion of data from linked secondary care data would help mitigate concerns of hypothesis testing in the same data to which the hypothesis was generated. PHE also have a long record of conducting epidemiological studies using active data collection methods and secondary care data through Hospital Episode Statistics (HES). Studies can be triggered by both the MHRA and PHE using established processes.

The self-controlled case-series method was specially designed for rapid unbiased assessment of vaccine safety issues (https://doi.org/10.1002/sim.2302). In this approach, cases act as their own controls as the incidence of the event of interest in pre-defined risk-periods following vaccination is compared to the incidence outside the risk period. However, as with the choice of data set it is important that the most appropriate study design is used for the issue identified.

Engaging with academia and other experts

The conduct of independent studies is also highly valuable and so the MHRA are working with PHE and the Health Protection Research Unit in Immunisation at LSHTM to establish a framework for the rapid conduct of epidemiological studies in OpenSAFELY17 (https://opensafely.org/). A template protocol is being written which will allow the investigation of key theoretical adverse events in the first instance and which can be rapidly updated to include additional events if the need arise.

The plans described in this report may be further adapted and extended and the MHRA continues to have dialogue with individual experts on surveillance plans. This may include incorporating additional methods, data sources or further collaboration with other UK and international academic partners into these plans.

What the MHRA does with the data we generate

The main objective of the safety monitoring process is to identify any new risks that may emerge as the vaccines are used. Such risks could include a new side effect, an apparent change in the nature of a known side effect, identification of factors that increase the chances of having a side effect, batch-related problems or issues related to inappropriate use of the vaccines.

If a new risk is confirmed, this will be fed into a continuous evaluation by the MHRA of the balance of benefits of a vaccine versus risks. The MHRA will consult the Commission on Human Medicines (CHM) and its Expert Groups and, if deemed necessary, regulatory action would be taken to minimise risk and support safe use of a given vaccine (e.g. adding warnings to the product information, sending out communications to healthcare professionals and patients, restricting its use). This would also be communicated to DHSC, PHE, devolved Governments and public health partners in the devolved nations to inform any decisions regarding the immunisation programme.

What information the MHRA will provide to the public on vaccine safety

The MHRA will operate a transparent process. On a regular basis, the MHRA will produce an up to date summary of the safety experience, including aggregate Yellow Card reports, on our website (https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-

adverse-reactions).

Coronavirus Vaccines

Summary of Yellow Card reporting

Published 26 May 2022

Data included: 9/12/2020 to 18/5/2022
This information is also available on the gov.uk website

Contents

www.gov.uk/mhra

Summary

At the time of this report, over 177,966 people across the UK have died within 28 days of a positive test for coronavirus (COVID-19). Vaccination is the single most effective way to reduce deaths and severe illness from COVID-19. A national immunisation campaign has been underway since early December 2020.

Three COVID-19 vaccines - the COVID-19 Pfizer/BioNTech Vaccine, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna – are currently being used in the UK. All have been authorised for supply by the Medicines and Healthcare products Regulatory Agency (MHRA) following a thorough review of safety, quality and efficacy information from clinical trials. In clinical trials, the vaccines showed very high levels of protection against symptomatic infections with COVID-19. Data are available on the impact of the vaccination campaign in reducing infections and illness in the UK.

The MHRA confirmed on 9 September 2021 that the COVID-19 vaccines made by Pfizer and AstraZeneca can be used as safe and effective booster doses. Following review of data for the COVID-19 Vaccine Moderna vaccine, the MHRA and Commission on Human Medicine (CHM) experts also concluded that this vaccine can be used as a safe and effective booster dose.

All vaccines and medicines have some side effects. These side effects need to be continuously balanced against the expected benefits in preventing illness.

The COVID-19 Pfizer/BioNTech Vaccine was evaluated in clinical trials involving more than 44,000 participants. The most frequent adverse reactions in these trials were pain at the injection site, fatigue, headache, myalgia (muscle pains), chills, arthralgia (joint pains), and fever; these were each reported in more than 1 in 10 people. These reactions were usually mild or moderate in intensity and resolved within a few days after vaccination. Adverse reactions were reported less frequently in older adults (over 55 years) than in younger people.

The COVID-19 Vaccine AstraZeneca was evaluated in clinical trials involving more than 23,000 participants. The most frequently reported adverse reactions in these trials were injection-site tenderness, injection-site pain, headache, fatigue, myalgia, malaise, pyrexia (fever), chills, and arthralgia, and nausea; these were each reported in more than 1 in 10 people. The majority of adverse reactions were mild to moderate in severity and usually resolved within a few days after vaccination. Adverse reactions were generally milder and reported less frequently in older adults (65 years and older) than in younger people.

The COVID-19 Vaccine Moderna was evaluated in clinical trials involving more than 30,000 participants. The most frequent adverse reactions in these trials were pain at the injection

site, fatigue, headache, myalgia (muscle pains), arthralgia (joint pains), chills, nausea/vomiting, axillary swelling/tenderness (swelling/tenderness of glands in the armpit), fever, injection site swelling and redness; these were each reported in more than 1 in 10 people. These reactions were usually mild or moderate in intensity and resolved within a few days after vaccination. Adverse reactions were reported less frequently in older adults (over 65 years) than in younger people.

The MHRA continually monitors safety during widespread use of a vaccine. We have in place a proactive strategy to do this. We also work closely with our public health partners in reviewing the effectiveness and impact of the vaccines to ensure the benefits continue to outweigh any possible side effects.

Part of our monitoring role includes reviewing reports of suspected side effects. Any member of the public or health professional can submit suspected side effects through the Yellow Card scheme. The nature of Yellow Card reporting means that reported events are not always proven side effects. Some events may have happened anyway, regardless of vaccination. This is particularly the case when millions of people are vaccinated, and especially when vaccines are being given to the most elderly people and people who have underlying illness.

As of 18 May 2022, for the UK, 170,867 Yellow Cards have been reported for the COVID-19 Pfizer/BioNTech Vaccine, 245,305 have been reported for the COVID-19 Vaccine AstraZeneca, 38,756 for the COVID-19 Vaccine Moderna and 1,708 have been reported where the brand of the vaccine was not specified.

For the COVID-19 Pfizer/BioNTech Vaccine, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna the overall reporting rate is around 2 to 5 Yellow Cards per 1,000 doses administered.

In the 7 days since the previous summary for 11 May 2022 we have received a further 242 Yellow Cards for the COVID-19 Pfizer/BioNTech Vaccine, 99 for the COVID-19 Vaccine AstraZeneca, 292 for the COVID-19 Vaccine Moderna and 13 where the brand was not specified.

It is important to note that Yellow Card data cannot be used to derive side-effect rates or compare the safety profile of COVID-19 vaccines as many factors can influence ADR reporting. Additionally, it is important to consider that a Yellow Card report can include reference to more than one vaccine associated with a suspected reaction where different vaccines have been used as third or booster doses.

For all COVID-19 vaccines, the overwhelming majority of reports relate to injection-site reactions (sore arm for example) and generalised symptoms such as ‘flu-like’ illness, headache, chills, fatigue (tiredness), nausea (feeling sick), fever, dizziness, weakness,

aching muscles, and rapid heartbeat. Generally, these happen shortly after the vaccination and are not associated with more serious or lasting illness.

These types of reactions reflect the normal immune response triggered by the body to the vaccines. They are typically seen with most types of vaccine and tend to resolve within a day or two. The nature of reported suspected side effects is broadly similar across age groups, although, as was seen in clinical trials and as is usually seen with other vaccines, they may be reported more frequently in younger adults.

A number of detailed assessments of safety topics have been undertaken and we have updated our advice on these topics accordingly. Overall, our advice remains that the benefits of the vaccines outweigh the risks in the majority of people. Further comments on use in specific populations and details on the specific safety topics can be found within Section titled Analysis of data.

Conclusion

Vaccines are the best way to protect people from COVID-19 and have already saved tens of thousands of lives. Everyone should continue to get their vaccination when invited to do so unless specifically advised otherwise.

- As with all vaccines and medicines, the safety of COVID-19 vaccines is being continuously monitored.
- The expected benefits of the vaccines in preventing COVID-19 and serious complications associated with COVID-19 far outweigh any currently known side effects in the majority of patients.

Further information on the type of suspected adverse reactions (ADRs) reported for the COVID-19 Pfizer/BioNTech Vaccine, the COVID-19 Vaccine AstraZeneca and the COVID-19 Vaccine Moderna is provided in Annex 1. It is important to read the attached guidance notes to ensure appropriate interpretation of the data.

Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) is the executive Agency of the Department of Health and Social Care that acts to protect and promote public health and patient safety, by ensuring that medicines and medical devices meet appropriate standards of safety, quality and efficacy.

The MHRA operates the Yellow Card scheme on behalf of the Commission on Human Medicines (CHM). The scheme collects and monitors information on suspected safety concerns or incidents involving vaccines, medicines, medical devices, and e-cigarettes. The scheme relies on voluntary reporting of suspected adverse incidents by healthcare professionals and members of the public (patients, users, or carers). The purpose of the scheme is to provide an early warning that the safety of a product may require further investigation. Further information about the Yellow Card scheme, including its contribution to identifying safety issues can be found on the Yellow Card website.

The MHRA is playing an active role in responding to the coronavirus pandemic. In relation to COVID-19 vaccines, the MHRA has authorised their supply following a rigorous review of their safety, quality and efficacy. The clinical trials of COVID-19 vaccines have shown them to be effective and acceptably safe; however, as part of its statutory functions, the MHRA is responsible for monitoring these vaccines on an ongoing basis to ensure their benefits continue to outweigh any risks. This is a requirement for all authorised medicines and vaccines in the UK. This monitoring strategy is continuous, proactive and based on a wide range of information sources, with a dedicated team of scientists reviewing information daily to look for safety issues or unexpected rare events.

This report summarises information received via the Yellow Card scheme and will be published regularly to include other safety investigations carried out by the MHRA under the COVID-19 Vaccine Surveillance Strategy.

What is a Yellow Card?

The Yellow Card scheme is a mechanism by which anybody can voluntarily report any suspected adverse reactions or side effects to the vaccine. It is very important to note that a Yellow Card report does not necessarily mean the vaccine caused that reaction or event. We ask for any suspicions to be reported, even if the reporter isn't sure if it was caused by the vaccine. Reports to the scheme are known as suspected adverse drug reactions (ADRs).

Many suspected ADRs reported on a Yellow Card do not have any relation to the vaccine or medicine and it is often coincidental that symptoms occurred around the same time as vaccination. The reports are continually reviewed to detect possible new side effects that may require regulatory action, and to differentiate these from things that would have

happened regardless of the vaccine or medicine being administered, for instance due to underlying or undiagnosed illness.

It is therefore important that the suspected ADRs described in this report are not interpreted as being proven side effects of COVID-19 vaccines. A list of the possible side effects of COVID-19 Pfizer/BioNTech Vaccine, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna are provided in the product information document for healthcare professionals and the UK recipient information. These can also be found on the Coronavirus Yellow Card reporting site.

This public summary provides an overview of all UK suspected ADRs associated with the new COVID-19 vaccines (the COVID-19 Pfizer/BioNTech Vaccine, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna), and the MHRA's analysis of the data, between 9 December 2020 and 18 May 2022 (inclusive). A glossary of key terms is provided in Annex 2.

If identified, information on new and emerging safety concerns will be provided in future editions of this report together with details of any resulting regulatory action or changes to advice on use of the vaccines.

Yellow Card reports

Vaccine doses administered

Data from the UK Public Health agencies show that at least 53,398,518 people have received their first vaccination in the UK by 18 May 2022, with 49,895,254 second doses administered. Individuals are also being invited for their booster vaccination if it has been 3 months since their second dose and they are either aged 18 and over or are aged 16 and over with a health condition that puts them at high risk from COVID-19. All children aged 12 to 15 are now eligible to receive a first dose and second dose of vaccine. Some children aged 5 to 11 have been eligible for a first and second dose of the COVID-19 vaccine if either they have a condition that means they are at high risk of serious illness from COVID-19 or they live with someone who has a weakened immune system. All children aged 5 to 11 will be eligible for vaccination in the coming weeks.

Table 1: Number of people who have received the first dose of a vaccination for COVID-19 in the UK between 8 December 2020 and end of 18 May 2022.

Country	Number of doses
England	44,895,197
Wales	2,559,001
Northern Ireland	1,428,726
Scotland	4,515,594

Table 2: Number of people who have received the second dose of a vaccination for COVID-19 in the UK between 8 December 2020 and end of 18 May 2022.

Country	Number of doses
England	41,928,298
Wales	2,418,070
Northern Ireland	1,342,791
Scotland	4,206,095

As of 18 May 2022, an estimated 26.8 million first doses of the COVID-19 Pfizer/BioNTech Vaccine and 24.9 million first doses of the COVID-19 Vaccine AstraZeneca had been administered, and around 24.2 and 24.1 million second doses each of the COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine AstraZeneca respectively. An approximate 1.7 million first doses and approximately 1.5 million second doses of the COVID-19 Vaccine Moderna have also now been administered. An estimated 30.1 million third or booster doses of COVID-19 Pfizer/BioNTech, 56,600 third or booster doses of COVID-19 Vaccine AstraZeneca and 9.4 million doses of COVID-19 Vaccine Moderna have been given. These figures are based on numbers of exposures reported individually by the individual nations which are extrapolated to produce an estimate of the total number of doses. Data are not always reported weekly and can be updated for historical dates when vaccinations are recorded on the relevant system. Therefore, data for this may be incomplete and the resulting estimates are approximate.

The estimated number of doses administered differs from the estimated number of people vaccinated due to the different data sources used.

As of 18 May 2022, an estimated 39,585,631 people had received their booster or additional vaccination in the UK. The priority groups being offered a booster dose of coronavirus (COVID-19) vaccine for this part of the vaccination campaign include people aged 16 years and over, health and social care workers and the clinically vulnerable.

Table 3: Number of people who have received the third or booster dose of a vaccination for COVID-19 in the UK between 8 December 2020 and end of 18 May 2022.

Country	Number of doses
England	32,895,235
Wales	2,034,790
Northern Ireland	1,119,584
Scotland	3,536,022

Yellow Card reporting trends

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have been. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in

such reports. **The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines**. The MHRA may also refer to ‘cases’ as opposed to ‘reports’ within the analysis of the Yellow Card data; these typically refer to ADR reports that have undergone medical assessment and are considered to meet certain criteria for diagnosis of the reported event and have at least a plausible association with the vaccine. All cases and reports are kept under continual review in order to identify possible new risks.

Up to and including 18 May 2022, the MHRA received and analysed 170,867 UK Yellow Cards from people who have received the COVID-19 Pfizer/BioNTech Vaccine. These reports include a total of 491,839 suspected reactions (i.e. a single report may contain more than one symptom). The first report was received on 9 December 2020.

Up to and including 18 May 2022, the MHRA received and analysed a total of 245,305 UK reports of suspected ADRs to the COVID-19 Vaccine AstraZeneca. These reports include a total of 868,997 suspected reactions (a single report may contain more than one symptom). The first report was received on 4 January 2021.

Up to and including 18 May 2022, the MHRA received and analysed a total of 38,756 UK reports of suspected ADRs to the COVID-19 Vaccine Moderna. These include a total 128,525 suspected reactions (a single report may contain more than one symptom). The first report was received on 7 April 2021.

Additionally, up to and including 18 May 2022, the MHRA received 1,708 Yellow Card reports where the brand of vaccine was not specified by the reporter.

In the 7 days since the previous summary for 11 May 2022 we have received a further 242 Yellow Cards for the COVID-19 Pfizer/BioNTech Vaccine, 99 for the COVID-19 Vaccine AstraZeneca, 292 for the COVID-19 Vaccine Moderna and 13 where the brand was not specified. Please note that a Yellow Card report can include more than one vaccine suspected to have caused a reaction where different vaccines have been used as third or booster doses.

It is important to note that Yellow Card data cannot be used to derive side effect rates or compare the safety profile of COVID-19 vaccines as many factors can influence ADR reporting.

Table 4: Number of suspected ADR reports received in the UK up to and including 18 May 2022.

	Number of reports			
Country	**COVID-19 Pfizer/ BioNTech Vaccine**	**COVID-19 Vaccine AstraZeneca**	**COVID-19 Vaccine Moderna**	**Brand unspecified**
England	133,238	202,046	30,988	1,020
Wales	8,247	10,859	2,287	93
Northern Ireland	3,010	2,993	153	21
Scotland	12,835	17,486	3,335	172

The figures in Table 4 are based upon the postcode provided by the reporter. The sums of the reports in the table will not equal the total reports received for each vaccine as postcode may not have always been provided or may have been entered incorrectly. It is important to note that the number of reports received for each country does not directly equate to the number of people who may have experienced adverse reactions and therefore cannot be used to determine the incidence of reactions. ADR reporting rates are influenced by many aspects, including the extent of use.

We are working with public health bodies and encouraging all healthcare professionals and patients alike to report any suspected ADRs to the Yellow Card scheme. As expected, reports gradually increase in line with an increase in doses administered.

The overall reporting rate for first, second and third or booster doses is in the order of 2 to 5 Yellow Cards per 1,000 doses administered for the COVID-19 Pfizer/BioNTech Vaccine, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna. It is known from the clinical trials that the more common side effects for all vaccines can occur at a rate of more than one in 10 doses (for example, local reactions or symptoms resembling transient flu-like symptoms).

Analysis of Data

One of the MHRA's main roles is to continually monitor the safety of medicines and vaccines during widespread use, and we have in place a proactive strategy to do this for COVID-19 vaccines. We also work closely with our public health partners in reviewing the effectiveness and impact that the vaccines are having to ensure benefits continue to outweigh any possible side effects. In addition, we work with our international counterparts to gather information on the safety of vaccines in other countries.

Given the huge scale of the COVID-19 immunisation programme, with many millions of doses of vaccines administered over a relatively short time period, vigilance needs to be continuous, proactive and as near real-time as is possible. The importance of this is two-fold. First, we need to rapidly detect, confirm, and quantify any new risks and weigh these against the expected benefits. We can then take any necessary action to minimise risks to individuals.

Secondly, we need to very quickly establish if any serious medical events which are temporally related to vaccination are merely a coincidental association. These associations are likely while we are still in the midst of a major national vaccination programme, and because many of the millions of people offered the vaccine in the early phase of a vaccination campaign were elderly and/or had underlying medical conditions, which increases the likelihood of unrelated illnesses occurring soon after vaccination. As mentioned above, the nature of Yellow Card reporting means that reported events are not always proven adverse reactions, and some may have happened regardless of vaccination.

Yellow Card reports of suspected ADRs are evaluated, together with additional sources of evidence, by a team of safety experts to identify any new safety issues or side effects. We apply statistical techniques that can tell us if we are seeing more events than we would expect to see, based on what is known about background rates of illness in the absence of vaccination. This aims to account for factors such as coincidental illness. We also look at the clinical characteristics to see if new patterns of illness are emerging that could indicate a new safety concern.

We supplement this form of safety monitoring with other epidemiology studies including analysis of data on national vaccine usage, anonymised GP-based electronic healthcare records and other healthcare data to proactively monitor safety. We also take into account the international experience based on data from other countries using the same vaccines. These combined safety data enables the MHRA to detect side effects or safety issues associated with COVID-19 vaccines. As well as confirming new risks, an equally important objective of monitoring will be to quickly rule out risks – in other words to confirm that the vaccine is not responsible for a suspected side effect and to provide reassurance on its safety.

Overall safety

As with any vaccine, COVID-19 vaccines will cause side effects in some people. The total number and the nature of the majority of Yellow Cards reports received so far is not unusual for a new vaccine for which members of the public and healthcare professionals are encouraged to report any suspected adverse reaction.

As highlighted above, it is known from the clinical trials that the most common side effects for all vaccines can occur at a rate of more than one per 10 doses (such as local reactions, symptoms resembling transient flu-like symptoms). Overall, Yellow Card reporting is therefore lower than the reporting rate of possible side effects from the clinical trials, although we generally do not expect all suspected side effects to be reported on Yellow Cards. The primary purpose of Yellow Card reporting is to detect new safety concerns.

For all COVID-19 vaccines, detailed review of all reports has found that the overwhelming majority relate to injection-site reactions (sore arm for example) and generalised symptoms such as a ‘flu-like’ illness, headache, chills, fatigue (tiredness), nausea (feeling sick), fever, dizziness, weakness, aching muscles, and rapid heartbeat. Generally, these happen shortly after the vaccination and are not associated with more serious or lasting illness. These types of reaction reflect the acute immune response triggered by the body to the vaccines, are typically seen with most types of vaccine and tend to resolve within a day or two. The nature of reported suspected ADRs across all ages is broadly similar, although, as seen in the clinical trials and as is usually seen with other vaccines, they may be reported more frequently in younger adults.

As we receive more reports of these types of reactions with more exposure to the COVID-19 vaccines, we have built a picture of how individuals are experiencing them and the different ways that side effects may present in people. Some people have reported a sudden feeling of cold with shivering/shaking accompanied by a rise in temperature, often with sweating, headache (including migraine-like headaches), nausea, muscle aches and feeling unwell, starting within a day of having the vaccine. Similar to the flu like illness reported in clinical trials, these effects may last a day or two.

It is important to note that it is possible to have caught COVID-19 and not realise until after vaccination. If other COVID symptoms are experienced or fever is high and lasts longer than two or three days, vaccine recipients should stay at home and arrange to have a test.

A number of detailed assessments of safety topics have been undertaken and we have updated our advice on these topics accordingly. Overall, our advice remains that the benefits of the vaccines outweigh the risks in the majority of people. Further comments on use in specific populations and details on the following safety topics can be found below.

Comments on safety in specific populations

Safety of COVID-19 vaccines in pregnancy

The MHRA closely monitors the safety of COVID-19 vaccine exposures in pregnancy, including published information as well as Yellow Card reports for COVID-19 vaccines used in pregnancy. These reports have been reviewed by the independent experts of the CHM's COVID-19 Vaccines Benefit Risk Expert Working Group and by the Medicines for Women's Health Expert Advisory Group (MWHEAG).

Pregnant women have the same risk of getting COVID-19 as non-pregnant women but they may be at an increased risk of becoming severely ill, particularly if they get infected in the third trimester or if they also have underlying medical problems, compared to non-pregnant women. The current advice of the Joint Committee on Vaccination and Immunisation (JCVI) is that the COVID-19 vaccines, including booster doses, should be offered to those who are pregnant as a clinical risk group in the COVID-19 vaccination programme. The COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna vaccines are currently the preferred vaccines for use during pregnancy and can be given at any stage in pregnancy.

The numbers of Yellow Card reports for pregnant women are low in relation to the number of pregnant women who have received COVID-19 vaccines to date (more than 100,000 women in England have given birth up to end of January 2022[1] after receiving at least 1 dose of COVID-19 vaccine during or shortly before pregnancy and more than 40,000 women in Scotland and Wales have received at least 1 dose whilst pregnant up to end March 2022). Pregnant women have reported similar suspected reactions to the vaccines as people who are not pregnant. Reports of miscarriage and stillbirth are also low in comparison to how commonly these events occurred in the UK outside of the pandemic. A few reports of commonly occurring congenital anomalies and obstetric events have also been received. There is no pattern from the reports to suggest that any of the COVID-19 vaccines used in the UK, or any reactions to these vaccines, increase the risk of miscarriage, stillbirths, congenital anomalies or birth complications.

Sadly, miscarriage is estimated to occur in about 20 to 25 in 100 pregnancies in the UK and most occur in the first 12 to 13 weeks of pregnancy (the first trimester). Published studies from the USA[2] and Norway[3] have compared miscarriage rates for vaccinated and unvaccinated women who were pregnant over the same time periods. The studies included

[1] Number of vaccinations during pregnancy are updated when data is made available by the UK Public Health bodies
[2] Kharbanda EO, et al. Spontaneous abortion following COVID-19 vaccination during pregnancy. JAMA. doi:10.1001/jama.2021.15494
[3] Magnus, MC et al. Covid-19 Vaccination during Pregnancy and First-Trimester Miscarriage N Engl J Med 2021; 385:2008-2010 DOI: 10.1056/NEJMc2114466

data from a large number of women (more than 15,000) who received the COVID-19 Pfizer/BioNTech Vaccine or COVID-19 Vaccine Moderna. Both studies found that the occurrence of miscarriage was equally likely amongst unvaccinated women as amongst women at the same stage of pregnancy who were vaccinated in the previous 3 to 5 weeks. These studies provide strong evidence for no increased risk of miscarriage in association with the mRNA vaccines in current use. Data on the COVID-19 Vaccine AstraZeneca is less extensive but is consistent with these findings.

Evidence for pregnancy outcomes other than miscarriage is accumulating as more pregnancies reach full term. Currently available evidence does not suggest any increased risks of pregnancy complications, stillbirths, preterm births or adverse neonatal outcomes following vaccination in later pregnancy.

Stillbirths are sadly estimated to occur in about 1 in 200 pregnancies in the UK. Information from surveillance by UKHSA (formerly Public Health England) has found similar rates of stillbirth amongst (more than 125,000) women who were vaccinated before or during pregnancy and those who gave birth over the same period and were unvaccinated. Likewise, surveillance by Public Health Scotland[4] and the COPS study[5] has found similar rates of perinatal mortality (including stillbirths) amongst (more than 15,700) women who were vaccinated during pregnancy and those who gave birth over the same period and who were unvaccinated and not infected with COVID-19.

Although, like most vaccines and medicines, clinical trials of COVID-19 vaccines in pregnant women were not carried out prior to use of the vaccines in the general population, there is now growing evidence from clinical use which provides reassurance on the safety of the vaccines in pregnancy. This adds to the evidence from non-clinical studies of the COVID-19 vaccines which have not raised any concerns about safety in pregnancy. The COVID-19 vaccines do not contain organisms that can multiply in the body, so they cannot infect an unborn baby in the womb.

The product information for COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna has been updated to reflect that the available data are reassuring on safety and that the vaccines can be used during pregnancy.

The MHRA will continue to closely monitor safety data for use of the COVID-19 vaccines in pregnancy, including through evaluation of electronic healthcare record data.

[4] Public ?Health Scotland, COVID-19 Statistical report https://publichealthscotland.scot/publications/covid-19-statistical-report/covid-19-statistical-report-11-may-2022/

[5] Stock SJ, et al SARS-CoV-2 infection and COVID-19 vaccination rates in pregnant women in Scotland Nature Medicine 2022 https://www.nature.com/articles/s41591-021-01666-2 .

Safety of COVID-19 vaccines in those breastfeeding

The MHRA closely monitors the safety of COVID-19 vaccines during breastfeeding, including evaluation of Yellow Card reports for COVID-19 vaccines from breastfeeding women. These reports have been reviewed by the independent experts of the CHM's COVID-19 Vaccines Benefit Risk Expert Working Group, by paediatric and breastfeeding experts.

There is no current evidence that COVID-19 vaccination while breastfeeding causes any harm to breastfed children or affects the ability to breastfeed.

COVID-19 vaccines do not contain live components and there is no known risk associated with being given a non-live vaccine whilst breastfeeding. The current advice of the Joint Committee on Vaccination and Immunisation (JCVI) is that breastfeeding parents may be offered any suitable COVID-19 vaccine depending on their age.

We have received about 4,000 Yellow Card reports from women breastfeeding at the time of vaccination. Most of these women reported only suspected reactions in themselves which were similar to reports for the general population, with no effects reported on their milk supply or in their breastfed children.

A small number of women have reported decreases in their milk supply, most of which were transient, or possible reactions in their breastfed child. A number of factors can affect milk supply and infant behaviour, including general maternal health, amount of sleep, and anxiety. The symptoms reported for the children (high temperature, rash, diarrhoea, vomiting and general irritability) are common conditions in children of this age, so some of the effects reported may have occurred by coincidence.

The product information for COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna has been updated to reflect that the available data are reassuring on safety and that the vaccines can be used during breastfeeding.

A small number of women may experience a reduction in their breast milk production and it may be helpful for breastfeeding women to know how to maintain their breast milk supply, particularly if they are feeling unwell. The NHS website has a good resource for this: https://www.nhs.uk/start4life/baby/breastfeeding/.

Suspected side effects reported in individuals under 18 years old

The MHRA closely monitors the safety of COVID-19 vaccine exposures in individuals under 18 years old, including Yellow Card reports for COVID-19 vaccines used in this age group.

Up to the 18 May 2022 there have been an estimated 3.9 million first doses, 2.2 million second doses, and 0.3 million additional or booster doses of the COVID-19 Pfizer/BioNTech Vaccine given to under 18s; approximately 11,600 first doses and 8,800 second doses of the COVID-19 Vaccine AstraZeneca given to this population; and 2,100 first doses and 1,700 second doses, and 3,100 additional or booster doses of the COVID-19 Vaccine Moderna given to individuals under 18. There has been extremely limited use of COVID-19 Vaccine AstraZeneca as boosters in those under 18 years.

The MHRA has received 3,761 UK reports of suspected ADRs for the COVID-19 Pfizer/BioNTech Vaccine in which the individual was reported to be under 18 years old, 262 reports for the COVID-19 Vaccine AstraZeneca, 30 for the COVID-19 Vaccine Moderna and 27 where the brand of vaccine was unspecified.

For the COVID-19 Pfizer/BioNTech Vaccine, which is currently the preferred COVID-19 vaccine for the under 18s age group in the UK vaccination programme, the experience reported in under 18s is similar to that identified in the general population and a review of these reports does not raise any additional safety topics specific to this age group. This includes the different age subgroups (5-11, 12-15 and 16-17 year olds). Reporting rates for 5-11 year olds, 12-15 year olds and 16-17 year olds are all around 1 per 1,000 doses. This is approximately half the reporting rate for the COVID-19 Pfizer/BioNTech Vaccine for those 18 years and over, which is around 2 per 1,000 doses.

As COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna are not the preferred vaccines in under 18s there is insufficient experience in this age group to be able to make similar estimates.

There has been a small number of reports for myocarditis and pericarditis (inflammation of the heart) in individuals under 18 years both in the UK and internationally. This is a recognised potential risk with the COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna and the MHRA is closely monitoring these events. Further information surrounding these very rare reports of myocarditis and pericarditis within this population can be found within the specific section on this safety topic later in the summary. We will continue to closely monitor the safety of the COVID-19 vaccines in those under 18 years old.

Suspected side effects reported in individuals receiving a booster vaccination

Safety monitoring plans have been agreed to ensure action can be taken on any emerging safety concerns from supplementary or booster doses.

As of 18 May 2022, an estimated 39.6 million COVID-19 third doses and booster doses have been administered in the UK. The COVID-19 Pfizer/BioNTech Vaccine and COVID-19

Vaccine Moderna are the preferred vaccines in the UK booster programme and make up the vast majority of doses administered.

Up to the 18 May 2022 the MHRA has received 31,382 UK reports of suspected ADRs where the COVID-19 Pfizer/BioNTech Vaccine was reported to be the booster dose, 560 reports where the COVID-19 Vaccine AstraZeneca was reported to be the booster dose, 17,594 reports where the COVID-19 Vaccine Moderna was reported to be the booster dose and 192 reports where the brand of vaccine booster was unspecified.

For the COVID-19 Pfizer/BioNTech Vaccine this represents a reporting rate of 1 report per 1,000 third or booster doses and for the COVID-19 Vaccine Moderna there is an estimated 2 reports per 1,000 third or booster doses. Both of these are lower than the reporting rate for COVID-19 vaccines for all vaccine doses combined, which is between 2-5 reports per 1,000 doses. For the COVID-19 Vaccine AstraZeneca there has been very limited number of booster doses in the UK and a very small number of reports. There is insufficient experience with COVID-19 Vaccine AstraZeneca as a booster vaccine to be able to make similar estimates of reporting rates.

The nature of events reported with third and booster doses is similar to that reported for the first two doses of the COVID-19 vaccines, and the vast majority of reports relate to expected reactogenicity events. Review of third and booster dose reports does not raise any new safety concerns. As part of the MHRA's booster safety monitoring strategy, reports of suspected adverse events following COVID-19 boosters given at the same time as seasonal flu vaccines have been closely monitored, and no new safety concerns have been identified in this data either.

There have been a small number of reports of suspected myocarditis and pericarditis (inflammation of the heart) following booster doses with Pfizer/BioNTech and Moderna COVID-19 vaccines. This is a recognised potential risk with the COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna and the MHRA is closely monitoring these events. The reports after booster doses are extremely rare and there is no indication that these events are more serious after boosters. Further information surrounding these very rare reports of suspected myocarditis and pericarditis can be found within the specific section on this safety topic later in the summary.

We will continue to closely monitor the safety of booster and third doses of the COVID-19 vaccines.

Comments on specific safety topics

The following reports reflect data up to 18 May 2022. The glossary provides an explanation of the clinical terms used.

Anaphylaxis (severe allergic reactions)

On 9 December 2020, the MHRA issued preliminary guidance on severe allergic reactions after administration of the COVID-19 Pfizer/BioNTech Vaccine due to early reports of anaphylaxis. Following further detailed review, this advice was amended on 30 December 2020 to the current advice. The advice is that people with a previous history of severe allergic reactions to any ingredients of the vaccine should not receive it. On 14 December 2021 it was announced that following a CHM review of the Yellow Card data on anaphylaxis after the primary course and boosters there would be a temporary suspension of the post vaccination 15-minute monitoring time for the majority of individuals. This helped to accelerate the public health response to the Omicron variant. On 5 May the 15-minute observation period after vaccination with the COVID-19 Pfizer/BioNTech or Moderna vaccines was removed for individuals aged 12 years and over and who have no history of a severe allergic reaction (as outlined in the Green Book[6] advice.) This followed careful review of the safety data by MHRA and advice from the CHM. A temporary suspension of the 15-minute observation period for children aged 5-11 years remains in place and this will be reviewed on a regular basis. The 15-minute observation period will remain in place for the small number of people who may have previously suffered anaphylaxis or other allergic reactions to a food, insect sting and most medicines or vaccines. The temporary suspension of the 15-minute observation time for children aged 5-11 years is under regular review by the CHM and the COVID-19 Vaccines Benefit Risk Expert Working Group.

Widespread use of the vaccine suggests that severe allergic reactions to the COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna are very rare. Anaphylaxis can also be a very rare side effect associated with most other vaccines.

The MHRA continues to monitor reports of severe allergic reactions with the COVID-19 Pfizer/BioNTech Vaccine and has received 663 UK spontaneous adverse reactions associated with anaphylaxis or anaphylactoid reactions. Severe allergic reactions to the COVID-19 Pfizer/BioNTech Vaccine remain very rare. The MHRA's guidance remains that those with a previous history of allergic reactions to the ingredients of the vaccine should not receive it.

The MHRA is closely monitoring reports of anaphylaxis with the COVID-19 Vaccine Moderna and has received 93 reports of anaphylaxis in association with the vaccine. Anaphylaxis is a potential side effect of the vaccine, and it is recommended that those with known hypersensitivity to the ingredients of the vaccine should not receive it.

COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna are the preferred vaccines in the UK booster programme. Reports of anaphylaxis or anaphylactoid reactions

[6] The Green Book has the latest information on vaccines and vaccination procedures, for vaccine preventable infectious diseases in the UK.

remain very rare after booster doses. Analysis of the data shows that these events are about 5 times lower after booster doses compared to the first dose.

The MHRA also closely monitors reports of anaphylaxis or anaphylactoid reactions with the COVID-19 Vaccine AstraZeneca and has received 886 UK spontaneous adverse reactions associated with anaphylaxis or anaphylactoid reactions reported and such reports are very rare. The product information reflects the fact that reports of anaphylaxis have been received for the COVID-19 Vaccine AstraZeneca.

Bell’s palsy

Bell's palsy (BP) is temporary weakness or paralysis affecting one side of the face that develops gradually; most people recover from this condition within a few months. BP is known to be associated with a number of infectious diseases, including the SARS-CoV-2 virus. Reports of suspected BP following COVID-19 vaccination have been continuously reviewed by the MHRA. Whilst reporting of BP following COVID-19 vaccination is rare, evidence based on the latest available data shows that there may be an increased risk of BP following COVID-19 vaccination. To raise awareness of this potential adverse event amongst healthcare professionals and patients, facial paralysis has been included in the product information for COVID-19 Vaccine AstraZeneca, COVID-19 Vaccine Pfizer/BioNTech and COVID-19 Vaccine Moderna. We will continue to monitor these events following COVID-19 vaccination.

Transverse myelitis

Transverse myelitis (TM) is a rare acute neurological disorder where parts of the spinal cord are inflamed. TM is known to be associated with a number of viruses, such as the herpes and influenza virus. The MHRA has continually monitored reports of suspected transverse myelitis following COVID-19 vaccination since the start of the vaccination programme. As of 18 May 2022, we have received 124 reports of suspected TM following administration of COVID-19 AstraZeneca, 39 reports following administration of COVID-19 Pfizer/BioNTech Vaccine and 7 reports following administration of COVID-19 vaccine Moderna. There were no reports of fatal events following suspected TM. Whilst the incidence rate of this adverse event with any of the COVID-19 vaccines used in the UK remains extremely rare (less than 1 report per 100,000 doses of each vaccine), the available evidence reviewed by the MHRA suggests an association between TM and COVID-19 AstraZeneca vaccine is possible. Due to the serious nature of this adverse event and as a precaution, the product information has been updated to raise healthcare professionals’ and patients’ awareness of the signs and symptoms associated with TM which may include muscle weakness, localised or radiating back pain, bladder and bowel symptoms and changes in sensation. It is recommended that patients who had an episode of transverse myelitis following the first dose of COVID-19 vaccine AstraZeneca should not receive a second dose of this vaccine.

Thrombo-embolic (blood clotting) events with concurrent low platelets

The MHRA has undertaken a thorough review into UK cases of an extremely rare and unlikely to occur specific type of blood clot in the brain, known as cerebral venous sinus thrombosis (CVST) occurring together with low levels of platelets (thrombocytopenia) following vaccination with the COVID-19 Vaccine AstraZeneca. It has also considered other blood clotting reports (thromboembolic events) alongside low platelet levels.

This scientific review concluded that the evidence of a link with COVID-19 Vaccine AstraZeneca is likely and an announcement was made on 7 April 2021 with a further statement on 7 May 2021. We have continued to publish the latest breakdown of all cases of these extremely rare side effects on a weekly basis.

Anyone who experienced cerebral or other major blood clots occurring with low levels of platelets after their first vaccine dose of COVID-19 Vaccine AstraZeneca should not have further doses. Anyone who did not have these side effects should come forward for their second dose when invited.

Anyone who experiences any of the following from around 4 days after vaccination should seek medical advice urgently:

- a severe headache that is not relieved with simple painkillers or gets worse or feels worse when you lie down or bend over
- an unusual headache that may be accompanied by blurred vision, confusion, difficulty with speech, weakness, drowsiness or seizures (fits)
- rash that looks like small bruises or bleeding under the skin beyond the injection site
- shortness of breath, chest pain, leg swelling or persistent abdominal (tummy) pain.

Up to 18 May 2022, the MHRA had received Yellow Card reports of 443 cases of major thromboembolic events (blood clots) with concurrent thrombocytopenia (low platelet counts) in the UK following vaccination with COVID-19 Vaccine AstraZeneca. Fifty-one of the 443 reports have been reported after a second dose. Of the 443 reports, 221 occurred in females, and 217 occurred in males aged from 18 to 93 years. The overall case fatality rate was 18% with 81 deaths, six of which occurred after the second dose.

Cerebral venous sinus thrombosis was reported in 160 cases (average age 46 years) and 283 had other major thromboembolic events (average age 54 years) with concurrent thrombocytopenia. The estimated number of first doses of COVID-19 Vaccine AstraZeneca administered in the UK by 18 May was 24.9 million and the estimated number of second doses was 24.1 million.

The overall incidence after first or unknown doses was 15.7 per million doses. Considering the different numbers of patients vaccinated with COVID-19 Vaccine AstraZeneca in different age groups, the data indicates that there is a higher reported incidence rate in the younger adult age groups following the first dose compared to the older groups (21.5 per million doses in those aged 18-49 years compared to 11.2 per million doses in those aged 50 years and over). The number of first doses given to those in the 18-49 years age group is estimated to be 8.5 million while an estimated 16.4 million first doses have been given to patients aged 50+ years. The MHRA advises that this evidence should be taken into account when considering the use of the vaccine. There is some evidence that the reported incidence rate is higher in females compared to men although this is not seen across all age groups and the difference remains small.

The overall incidence of thromboembolic events with concurrent low platelets after second doses was 2.1 cases per million doses. Taking into account the different numbers of patients vaccinated with COVID-19 Vaccine AstraZeneca in different age groups, the data indicates that there is a lower reported incidence rate in younger adult age groups following the second dose compared to the older groups (1.0 per million doses in those aged 18-49 years compared to 2.1 per million doses in those aged 50 years and over). The number of second doses given to those in the 18-49 years age group is estimated to be 8.1 million while an estimated 16.1 million second doses have been given to patients aged 50+ years. These rates after second doses should not be directly compared to the incidence rates reported after the first dose as the time for follow-up and identification of cases after second doses is more limited and differs across age groups. However, the data are reassuring, particularly regarding younger recipients where there is a significantly lower incidence after the second dose compared to the first, and there is overall no indication of an increased risk of these events after the second dose in any age group. Anyone who did not have these side effects should come forward for their second dose when invited.

These cases have also been analysed by the independent advisory body, the CHM's COVID-19 Vaccines Benefit Risk Expert Working Group, which includes lay representatives and advice from leading haematologists.

On the basis of this ongoing review, the advice remains that the benefits of the vaccine outweigh the risks in the majority of people.

Table 5: Number of suspected thrombo-embolic events with concurrent thrombocytopenia ADR cases received for the COVID-19 Vaccine AstraZeneca in the UK up to and including 18 May 2022.

Country	Number of cases
England	349

Wales	14
Northern Ireland	11
Scotland	38
Unknown	31

Table 6: Number of UK suspected thrombo-embolic events with concurrent thrombocytopenia ADR cases received for the COVID-19 Vaccine AstraZeneca by patient age up to and including 18 May 2022.

Age range (years)	Number of cases	Number of fatal cases
18-29	31	7
30-39	49	10
40-49	111	15
50-59	108	22
60-69	62	11
70-79	40	7
80-89	6	3
90-99	2	1
Unknown	34	5
Total	**443**	**81**

Table 7: Number of UK suspected thrombo-embolic events with concurrent thrombocytopenia ADR cases received for the COVID-19 Vaccine AstraZeneca by patient sex up to and including 18 May 2022.

Sex	Number of cases	Number of fatal cases
Male	217	35
Female	221	45

Unknown	5	1
Total	**443**	**81**

Up to 18 May 2022, the MHRA had received Yellow Card reports of 32 cases of major thromboembolic events (blood clots) with concurrent thrombocytopenia (low platelet counts) in the UK following use of the COVID-19 Pfizer/BioNTech Vaccine. These events occurred in 13 females, and 18 males aged from 18 to 91 years, and the overall case fatality rate was 13% with four deaths reported.

Up to 18 May 2022, the MHRA had received Yellow Card reports of 7 cases of major thromboembolic events (blood clots) with concurrent thrombocytopenia (low platelet counts) in the UK following the use of COVID-19 vaccine Moderna. These events occurred in 5 adult males and 2 adult females between the ages of 28-95. There have been no fatal cases reported.

To note, direct comparison of the summary provided here, and the analysis prints is not possible. This review includes reports of CVST or other thrombo-embolic events with concurrent thrombocytopenia. Blood clotting events without lowered platelets are described below.

Yellow Card reports may contain more than one reported reaction and the analysis prints are listed by individual reactions rather than whole reports. Therefore, summing the reactions listed in the prints will not equate to the total cases included within this summary.

Thrombo-embolic (blood clotting) events without concurrent low platelets

The MHRA has conducted a thorough review of events of cerebral venous sinus thrombosis (CVST) without concurrent low platelet levels following vaccination with the COVID-19 Vaccine AstraZeneca and sought advice from the CHM's Vaccine Benefit Risk Expert Working Group. Blood clotting events with lowered platelets are described in a separate section (above). The scientific review concluded that there is a possible link between CVST without low platelets and COVID-19 Vaccine AstraZeneca. The product information for COVID-19 Vaccine AstraZeneca has been updated to include information that CVST events not associated with low levels of blood platelets occurred extremely rarely. The majority of the CVST events occurred within the first four weeks following vaccination. A potential cause has not been identified.

The MHRA has also confirmed that the evidence to date does not suggest that the COVID-19 Vaccine AstraZeneca increases the risk of venous thromboembolism (i.e. deep vein

thrombosis/pulmonary embolism) in the absence of a low platelet count. The MHRA will continue to closely monitor reports of venous thromboembolism following COVID-19 vaccination.

Immune thrombocytopenia

Immune thrombocytopenia (ITP) is a condition where the immune system does not function correctly and becomes involved in destroying platelets, which can lead to bleeding; these events are usually short-lived and of minor severity. Reports of ITP following COVID-19 vaccination have been closely monitored by the MHRA. A recent thorough review of all the available evidence confirmed that this type of event is reported extremely rarely for COVID-19 vaccine AstraZeneca in the UK, at approximately 4 reports per million doses. In approximately 10-20% of the reports, patients had a history of ITP or an underlying condition known to be associated with ITP. Following the most recent review, the available data suggested a possible link between COVID-19 vaccine AstraZeneca and ITP, and the product information for this vaccine has been updated to include information on the occurrence of ITP.

Capillary Leak Syndrome

The MHRA has received 17 reports of suspected capillary leak syndrome (a condition where fluid leaks from the small blood vessels into the body) in the context of more than 49.1 million doses of COVID-19 Vaccine AstraZeneca given. Of these reports, 3 people had a history of capillary leak syndrome. This is an extremely rare relapsing-remitting condition and triggers for relapses are not well understood. As a precautionary measure, the MHRA is advising that COVID-19 Vaccine AstraZeneca is not used in people who have previously experienced episodes of capillary leak syndrome. The product information has been updated to reflect this advice.

Menstrual disorders (period problems) and unexpected vaginal bleeding

The MHRA is reviewing reports of suspected side effects of menstrual disorders (period problems) and unexpected vaginal bleeding following vaccination against COVID-19 in the UK. These reports are also being reviewed by the independent experts of the CHM's COVID-19 Vaccines Benefit Risk Expert Working Group and the Medicines for Women's Health Expert Advisory Group. The rigorous evaluation completed to date does not support a link between changes to menstrual periods and related symptoms and COVID-19 vaccines.

Up to 18 May 2022 a total of 51,211 suspected reactions relating to a variety of menstrual disorders have been reported after all three of the COVID-19 vaccines including heavier than usual periods, delayed periods and unexpected vaginal bleeding. These suspected reactions

have been reported in 39,903 individual Yellow Card reports (as each report may contain more than one suspected reaction). This is following approximately 74.1 million COVID-19 vaccine doses administered to women up to 18 May 2022. The number of reports of menstrual disorders and vaginal bleeding is low in relation to both the number of people who have received COVID-19 vaccines to date and how common menstrual disorders are generally.

The menstrual changes reported are mostly transient in nature. There is no evidence to suggest that COVID-19 vaccines will affect fertility and your ability to have children.

Whilst uncomfortable or distressing, period problems are extremely common and stressful life events can disrupt menstrual periods. Changes to the menstrual cycle have also been reported following infection with COVID-19 and in people affected by long-COVID. General advice about period problems and/or unexpected vaginal bleeding is available from the NHS website. It is important that anyone experiencing changes to their periods that are unusual for them, persist over time, or has any new vaginal bleeding after the menopause, following COVID-19 vaccination, should contact their doctor. Anyone presenting with menstrual disorders and/or unexpected vaginal bleeding following COVID-19 vaccination should be treated according to clinical guidelines for these conditions, as usual.

The MHRA continues to closely review reports of suspected side effects of menstrual disorders and unexpected vaginal bleeding.

Myocarditis and pericarditis (Inflammation of the heart)

The MHRA has undertaken a thorough review of both UK and international reports of suspected myocarditis and pericarditis following vaccination against COVID-19. There has been a consistent pattern of higher reporting of these suspected events with the COVID-19 Pfizer/BioNTech and COVID-19 Vaccine Moderna, and of these occurring more frequently in males. These reports have also been analysed by the government's independent advisory body, the CHM and its COVID-19 Vaccines Benefit Risk Expert Working Group. Following their advice, the product information for the COVID-19 Vaccine Moderna and COVID-19 Pfizer/BioNTech Vaccines was updated to inform of these reports and advise healthcare professionals and patients to be aware of important symptoms for myocarditis and pericarditis.

These reports are very rare, and the events reported are typically mild with individuals usually recovering within a short time with standard treatment and rest.

People should come forward for their second and booster vaccination when invited to do so, unless advised otherwise.

It is important that anyone who experiences new onset of symptoms such as chest pain, shortness of breath or feelings of having a fast-beating, fluttering, or pounding heart seeks medical attention.

Up to and including 18 May 2022, we have received 791 reports of myocarditis and 537 reports of pericarditis following use of the COVID-19 Pfizer/BioNTech Vaccine, as well as ten reports of carditis, five reports for viral myocarditis, four reports for infective pericarditis, three reports for viral pericarditis, two reports each for myocarditis mycotic and endocarditis, and one report each of constrictive pericarditis, pleuropericarditis, lupus pericarditis, non-infective endocarditis, infectious myocarditis, eosinophilic myocarditis, hypersensitivity myocarditis, myocarditis post infection, bacterial myocarditis, septic myocarditis and streptococcal endocarditis.

For COVID-19 Vaccine AstraZeneca there have been 228 reports of myocarditis and 220 reports of pericarditis following vaccination up to and including 18 May 2022 as well as eight reports for endocarditis, five reports for viral pericarditis, three reports for viral myocarditis, two reports each for bacterial endocarditis, carditis, and acute endocarditis, and one report each for infectious myocarditis, myocarditis post infection, autoimmune pericarditis and autoimmune myocarditis.

There have been 222 reports of myocarditis, 131 reports of pericarditis, three reports of carditis and one report each of hypersensitivity myocarditis, pleuropericarditis, viral myocarditis and endocarditis following use of COVID-19 Vaccine Moderna up to the same date.

Five fatal suspected myocarditis or pericarditis events have been reported associated with the COVID-19 Pfizer/BioNTech Vaccine and four fatal events associated with the COVID-19 Vaccine AstraZeneca. There have been no fatal myocarditis or pericarditis events reported with the COVID-19 Vaccine Moderna to date. Fatal events are being monitored closely and are carefully followed up to gather relevant information. The majority of fatal reports describe underlying illnesses in these patients that could provide alternative explanations for the events reported.

Based on reports of suspected ADRs in the UK, the overall reporting rate across all age groups for suspected myocarditis (including viral myocarditis), after first, second and booster or third doses, is 10 reports per million doses of COVID-19 Pfizer/BioNTech Vaccine and for suspected pericarditis (including viral pericarditis and infective pericarditis) the overall reporting rate is 7 reports per million doses. For COVID-19 Vaccine Moderna, the overall reporting rate for suspected myocarditis (including hypersensitivity myocarditis and viral myocarditis) is 18 per million doses and for suspected pericarditis (including pleuropericarditis) is 10 per million doses. For COVID-19 Vaccine AstraZeneca the overall reporting rate for suspected myocarditis (including viral myocarditis and infectious

myocarditis) is 5 per million doses and for suspected pericarditis (including viral pericarditis) is 5 per million doses. It should be noted that an individual report can contain more than one event and therefore the total number of reports will not be equal to the number of events.

When the reporting rate is calculated by age group (see Table 8) the reporting rate for suspected myocarditis and pericarditis is highest in the 18-29-year age group for the Pfizer/BioNTech and Moderna COVID-19 vaccines. A more even spread in reporting rates across the age groups is seen for AstraZeneca COVID-19 vaccine. For all vaccines there is a trend for decreased reporting in the older age groups.

Pfizer/BioNTech is currently the preferred COVID-19 vaccine for the under 18s age group in the UK vaccination programme, and for this vaccine there is no indication in the current data that there is an increased reporting rate of suspected myocarditis and pericarditis in this age group overall compared to young adults. Furthermore, the reporting rates for the 12-15 year and 16-17 year age group are lower than that in the young adult 18-29 age group after the first and second doses. Due to very limited experience in the 5–11 year age group it is not possible to reliably make the same estimations for this population. There have been no reports of suspected myo/pericarditis following booster doses in the under 18-year age group.

There are largely similar reporting rates between the first and second doses of the Pfizer/BioNTech and AstraZeneca COVID-19 vaccines. There is greater variability between first and second dose reporting rates with Moderna however the reporting rate estimates for Moderna may lack precision due to the more limited experience with Moderna in the UK and small numbers of suspected reports. This introduces more uncertainty into the data.

COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna are the preferred vaccines in the UK booster programme, and the reporting rates for suspected myocarditis and pericarditis following booster or third doses of these vaccines are lower than those estimated for the first and second doses; these events are very rare after booster doses. There is no indication that these events are more severe after booster doses compared to first and second doses; most reports describe mild events with a rapid recovery and are similar to those experienced after the first and second doses. There is extremely limited usage of COVID-19 Vaccine AstraZeneca as a booster. Due to this limited usage and very small numbers of reports of suspected myocarditis and pericarditis after booster doses, it is not possible to calculate a reliable reporting rate for the COVID-19 Vaccine AstraZeneca when used as a booster; no association has been established between myocarditis or pericarditis and the COVID-19 Vaccine AstraZeneca.

It is important to note that Yellow Card data cannot be used to compare the safety profile of COVID-19 vaccines as many factors can influence ADR reporting.

These reporting rates may also be subject to change as more experience is gathered in the UK.

Table 8: Reporting rates per million doses for UK ADR reports of suspected myocarditis and pericarditis associated with COVID-19 Vaccines, by patient age and dose, up to and including 18 May 2022.

Age range (years)	COVID-19 Pfizer/ BioNTech 1st or unknown dose	COVID-19 Pfizer/ BioNTech 2nd dose	COVID-19 Pfizer/ BioNTech 3rd or booster dose	COVID-19 Vaccine Moderna 1st or unknown dose	COVID-19 Vaccine Moderna 2nd dose	COVID-19 Vaccine Moderna 3rd or booster dose	COVID-19 Vaccine AstraZeneca 1st or unknown dose	COVID-19 Vaccine AstraZeneca 2nd dose
Under 18	14	11	Not calculated*	Not applicable**	Not applicable**	Not applicable**	Not applicable**	Not applicable**
18-29	25	28	17	62	70	19	10	16
30-39	23	23	15	59	55	21	14	12
40-49	20	19	12	49	31	15	13	9
50-59	9	17	8	Not calculated*	Not calculated*	8	8	8
60-69	7	14	6	Not calculated*	Not applicable**	7	7	6
70+	4	5	4	Not calculated*	Not applicable**	2	4	4

*There is currently insufficient data to calculate a reliable estimate of the reporting rate in the UK due to the relatively limited exposure and small numbers of suspected reports in these individuals.

**There have been no reports of suspected heart inflammation events received for individuals in these age groups.

Table 9*: Number of UK ADR reports associated with suspected myocarditis, pericarditis and other related terms received for the COVID-19 Vaccine AstraZeneca, COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna by patient age up to and including 18 May 2022.

Age range (years)	Number of reports		
	COVID-19 Pfizer/BioNTech Vaccine	COVID-19 Vaccine Moderna	COVID-19 Vaccine AstraZeneca
Under 18	79	0	0
18-29	383	120	31
30-39	310	97	48
40-49	139	52	116
50-59	98	22	104
60+	152	18	104
Unknown	149	34	48
Total	**1310**	**343**	**451**

* Due to the dynamic nature of the Yellow Card data these figures may change both as new cases are received, and as duplicate cases are identified and managed.

Table 10*: Number of UK ADR reports associated with suspected myocarditis, pericarditis and other related terms received for the COVID-19 Vaccine AstraZeneca, COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna by patient sex up to and including 18 May 2022.

Sex	Number of reports		
	COVID-19 Pfizer/BioNTech Vaccine	COVID-19 Vaccine Moderna	COVID-19 Vaccine AstraZeneca
Female	514	112	205
Male	758	221	236
Unknown	38	10	10
Total	**1310**	**343**	**451**

* Due to the dynamic nature of the Yellow Card data these figures may change both as new cases are received, and as duplicate cases are identified and managed.

Two large European epidemiological studies have estimated the excess risk of myocarditis following vaccination with COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna. One study showed that in a period of 7 days after the second dose of COVID-19 Pfizer/BioNTech Vaccine there were about 27 (95% CI 26 - 28) extra cases of myocarditis in 12-29 year old males per million compared to unvaccinated individuals, and for COVID-19 vaccine Moderna there were about 132 (95% CI 130 – 133) extra cases of myocarditis in 12-29 year old males per million. In another study, in a period of 28 days after the second dose of the COVID-19 Pfizer/BioNTech Vaccine there were 57 [95% CI 39 – 75] extra cases of myocarditis in 16-24 year old males per million compared to unvaccinated persons, and for COVID-19 vaccine Moderna there were 188 (95% CI 96 – 280) extra cases of myocarditis in 16-24 year old males per million individuals compared to unvaccinated individuals. These studies have shown that these events are very rare post vaccination with the mRNA vaccines, and that these events are more frequent in younger males. The findings of these studies are consistent with the trends seen in the Yellow Card data.

International data has shown that these suspected events have been observed to occur most frequently approximately 3 days after the first vaccine and 2 days after the second vaccine, and both UK and international data have identified that the large majority of suspected events occur within 7 days of vaccination. In the UK the body of evidence shows that there is similar frequency of reporting after the first and second dose.

Longer term follow up in both the UK and US to at least 90 days following identification of cases of suspected myocarditis after COVID-19 Pfizer/BioNTech and COVID-19 Vaccine Moderna found that the majority of individuals were fully recovered and back to normal activities.

Myocarditis and pericarditis happen very rarely in the general population, and it is estimated that in the UK there are about 60 new cases of myocarditis diagnosed per million patients per year and about 100 new cases of pericarditis diagnosed per million patients per year. Myocarditis is also known to be associated with COVID-19 infection, with an estimated 1,500 cases of myocarditis per million patients with COVID-19.

The MHRA will continue to closely monitor reports of suspected myocarditis and pericarditis with all currently authorised COVID-19 vaccines.

Delayed hypersensitivity reactions

The MHRA has been reviewing reports of skin reactions occurring around the vaccination site that appear a little while after vaccination. These reactions are suggestive of a delayed hypersensitivity reaction that occurs 4-11 days after vaccination. The reactions are

characterized by a rash, swelling and tenderness that can cover the whole upper arm and may be itchy and/or painful and warm to the touch. The majority of the reports received have been with the COVID-19 Vaccine Moderna and the product information for this vaccine has been updated to highlight the possibility of delayed injection site reactions.

The reactions are usually self-limiting and resolve within a day or two, although in some patients it can take slightly longer to disappear. Individuals who experience this reaction after their first dose may experience a similar reaction in shorter timeframe following the second dose, however, none of the reports received have been serious and people should still take their second dose when invited. Those who experience delayed skin reactions after their COVID-19 vaccination which do not resolve within a few days should seek medical advice.

Guillain-Barré Syndrome

Guillain-Barré Syndrome is a very rare condition which causes inflammation of the nerves and can lead to numbness, weakness and pain, usually in the feet, hands and limbs and can spread to the chest and face. Guillain-Barré Syndrome tends to affect both sides of the body at once. This condition is known to be associated with certain infectious diseases.

Up to and including the 18 May 2022, the MHRA has received 497 reports of suspected Guillain-Barré Syndrome with the COVID-19 Vaccine AstraZeneca and 29 reports of a related disease called Miller Fisher syndrome. Up to the same date, the MHRA has received 105 reports of Guillain-Barré Syndrome following use of the COVID-19 Pfizer/BioNTech Vaccine and 5 reports of Miller Fisher syndrome and for the COVID-19 Vaccine Moderna there have been 18 reports of Guillain-Barré Syndrome.

The MHRA has been closely monitoring and assessing reports of suspected Guillain-Barré Syndrome (GBS) received following administration of the COVID-19 vaccine. Following the most recent review of the available data the evidence of a possible association has strengthened. Therefore, following advice from the government’s independent advisory body, the CHM and its COVID-19 Vaccines Benefit Risk Expert Working Group, the product information for the COVID-19 Vaccine AstraZeneca was further updated to include GBS in the tabulated list of adverse reactions associated with the COVID-19 Vaccine AstraZeneca and to encourage healthcare professionals and the public to look out for signs of GBS.

The MHRA will continue to review reports of Guillain-Barré Syndrome received following vaccination with COVID-19 vaccines to further assess a possible association, with independent advice from its Vaccine Benefit-Risk Working Group.

Swelling of the vaccinated limb

There have been rare reports of extensive swelling of the vaccinated limb after receiving the COVID-19 Pfizer/BioNTech Vaccine. The product information has been updated to include

“extensive swelling of the vaccinated limb” as a side effect of the vaccine. This type of swelling is also recognised to occur with other (non-COVID-19) vaccines.

Facial swelling in those with a history of facial dermal fillers

Rare reports of facial swelling occurring 1-2 days after vaccination in vaccine recipients with a history of injection of facial dermal fillers were observed in the clinical trials for the COVID-19 Vaccine Moderna. Information about this possible side effect has been included in the product information for the COVID-19 Vaccine Moderna since it was first authorised for use.

The MHRA has also received Yellow Card reports of facial swelling in those with a history of injection of facial dermal fillers for the COVID-19 Pfizer/BioNTech Vaccine. A review of the world-wide ADR data for the COVID-19 Pfizer/BioNTech Vaccine found that, in most instances, the facial swelling was mild, transient and was localised to the site of the dermal filler. The product information for the COVID-19 Pfizer/BioNTech Vaccine has been updated to include facial swelling in those with a history of injection of facial dermatological fillers as a side effect of the vaccine.

Events with a fatal outcome

Vaccination and surveillance of large populations means that, by chance, some people will experience and report a new illness or events in the days and weeks after vaccination. A high proportion of people vaccinated early in the vaccination campaign were very elderly, and/or had pre-existing medical conditions. Older age and chronic underlying illnesses make it more likely that coincidental adverse events will occur, especially given the millions of people vaccinated. It is therefore important that we carefully review these reports to distinguish possible side effects from illness that would have occurred irrespective of vaccination.

Part of our continuous analysis includes an evaluation of natural death rates over time, to determine if any specific trends or patterns are occurring that might indicate a vaccine safety concern. Based on age-stratified all-cause mortality in England and Wales taken from the Office for National Statistics death registrations, several thousand deaths are expected to have occurred, naturally, within 7 days of the many millions of doses of vaccines administered so far, mostly in the elderly.

A recent study published by the Office for National Statistics (ONS) and the Office for Health Improvement and Disparities (OHID) analysed data on COVID 19 vaccination and mortality in young people during the coronavirus pandemic. The study found no indication of an increased risk of death from cardiac-related or other causes in those aged 12-29 years, following COVID-19 vaccination in the six weeks following vaccination. This is consistent with our own findings from our rigorous safety monitoring activities. The study also suggested that the excess in death registrations in young people in 2021 was due to delays

in the registration process and early indications of increased numbers of deaths due to non-vaccine related external causes. The study data were reviewed by the independent experts of the CHM's COVID-19 Vaccines Benefit Risk Expert Working Group who agreed with the conclusion of the report that COVID-19 vaccines were not associated with an increased risk of death in young people.

The MHRA has received 773 UK reports of suspected ADRs to the COVID-19 Pfizer/BioNTech Vaccine in which the patient died shortly after vaccination, 1,273 reports for the COVID-19 Vaccine AstraZeneca, 56 for the COVID-19 Vaccine Moderna and 46 where the brand of vaccine was unspecified. The majority of these reports were in elderly people or people with underlying illness. Usage of the vaccines has increased over the course of the campaigns and as such, so has reporting of fatal events with a temporal association with vaccination. However, this does not mean that there is a link between vaccination and the fatalities reported. Review of specific fatal reports is provided in the summaries above. The pattern of reporting for all other fatal reports does not suggest the vaccines played a role in these deaths.

A range of other isolated events or series of reports of non-fatal, serious suspected ADRs have been reported. These all remain under continual review, including thorough analysis of expected rates in the absence of vaccine. There are currently no indications of specific patterns or rates of reporting that would suggest the vaccine has played a role.

Conclusion

At the time of this report, over 177,966 people across the UK have died within 28 days of a positive test for coronavirus.

Vaccination is the single most effective way to reduce deaths and severe illness from COVID-19. A national immunisation campaign has been underway since early December 2020.

In clinical trials, the COVID-19 Pfizer/BioNTech Vaccine, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna have demonstrated very high levels of protection against symptomatic infection. Data are available on the impact of the vaccination campaign in reducing infections and illness in the UK.

All vaccines and medicines have some side effects. These side effects need to be continuously balanced against the expected benefits in preventing illness.

Following widespread use of these vaccines across the UK, the vast majority of suspected adverse reaction reports confirm the safety profile seen in clinical trials. Most reports relate to injection-site reactions (sore arm for example) and generalised symptoms such as a ‘flu-like’ illness, headache, chills, fatigue, nausea, fever, dizziness, weakness, aching muscles, and rapid heartbeat. Generally, these reactions are not associated with more serious illness and likely reflect an expected, normal immune response to the vaccines.

The expected benefits of the vaccines in preventing COVID-19 and serious complications associated with COVID-19 far outweigh any currently known side effects. As with all vaccines and medicines, the safety of COVID-19 vaccines is continuously monitored and benefits and possible risks remain under review.

We take every report of a suspected ADR seriously and encourage everyone to report through the Yellow Card scheme.

Annex 1 Vaccine Analysis Print

The attached Vaccine Analysis Prints contain a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme for the COVID-19 Pfizer/BioNTech Vaccine, the COVID-19 Vaccine AstraZeneca, the COVID-19 Vaccine Moderna and where the brand of the vaccine was not specified. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies.

This information does not represent an overview of the potential side effects associated with the vaccines. A list of the recognised adverse effects of COVID-19 vaccines is provided in the information for healthcare professionals and the recipient information here. These can also be found on the Coronavirus Yellow Card reporting site. Conclusions on the safety and risks of the vaccines cannot be made on the data shown in the Print alone.

When viewing the vaccine analysis print you should remember that:

- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the medicine or vaccine may have caused the adverse reaction. The existence of an adverse reaction report in the print does not necessarily mean that the vaccine has caused the suspected reaction.

- It may be difficult to tell the difference between something that has occurred naturally and a suspected adverse reaction. Sometimes these events can be part of the condition being treated rather than being caused by the vaccine.

- Many factors have to be considered when assessing whether the vaccine has caused a reported adverse reaction. When monitoring the safety of vaccines and medicines, MHRA staff carry out careful analysis of these factors.

For a medicine or vaccine to be considered safe, the expected benefits will be greater than the risk of having harmful reactions. It is important to note that most people take medicines and vaccines without having any serious side effects.

Vaccine Analysis Print – COVID-19 Pfizer/BioNTech Vaccine

Vaccine Analysis Print - COVID-19 Vaccine AstraZeneca

Vaccine Analysis Print – COVID-19 Vaccine Moderna

Vaccine Analysis Print - Brand unspecified

Annex 2 Glossary

Anaphylaxis or anaphylactoid reactions

Anaphylaxis is a severe and potentially life-threatening allergic reaction. These reactions can occur after an exposure to a trigger, such as a certain ingredient in foods or medicines or an insect sting. Anaphylaxis and anaphylactoid reactions can be treated with adrenaline.

Bell's palsy

Bell's palsy is a condition that causes temporary weakness or paralysis (lack of movement) of the muscles in one side of the face. It is the most common cause of facial paralysis. For most people, the facial paralysis is temporary. Viral infections such as those with herpes viruses have been linked to Bell's palsy.

Booster dose/vaccination

A COVID-19 booster vaccine dose helps improve the protection obtained from the first two doses of the vaccine. It helps give longer-term protection against getting seriously ill from COVID-19.

Capillary Leak Syndrome (CLS)

Capillary Leak Syndrome (CLS) occurs when fluid leaks from the small blood vessels into the body.

Cerebral venous sinus thrombosis (CVST)

Cerebral venous sinus thrombosis occurs when the brain's venous sinuses or the smaller veins draining into them are partially or completely blocked by a blood clot. This prevents blood from draining out of the brain. As a result, the oxygen supply to nerve cells may be impaired and blood cells can leak into the brain tissue causing damage to the brain (haemorrhagic infarction).

Clinical Practice Research Datalink (CPRD)

Clinical Practice Research Datalink (CPRD) is a real-world research service to support public health and clinical studies. CPRD is jointly sponsored by the Medicines and Healthcare products Regulatory Agency and the National Institute for Health Research (NIHR), as part of the Department of Health and Social Care. CPRD collects anonymised patient data from a network of GP practices across the UK.

Commission on Human Medicines (CHM)

The Commission on Human Medicines (CHM) advises ministers on the safety, efficacy and quality of medicinal products. For COVID-19 vaccines, the CHM has a COVID-19 Vaccines Safety Surveillance Methodologies Expert Working Group and a COVID-19 Vaccines Benefit Risk Expert Working Group.

Endocarditis

Endocarditis is inflammation of the inner lining of the heart (endocardium).

Epidemiology studies

Epidemiological studies include large numbers of people and are designed to compare the risk of a particular event in an exposed population, in this case those who have received a vaccine, to those who have not. They attempt to account for differences in the different groups to help us understand if any difference in risk is caused by the exposure. Epidemiological studies measure the risk of illness or death in an exposed population compared to that risk in an identical, unexposed population.

Guillain-Barré Syndrome

Guillain-Barré Syndrome is inflammation of the nerves and can lead to numbness, weakness and pain, usually in the feet, hands and limbs and can spread to the chest and face. This syndrome has been associated with viral infections such as the flu.

Immune thrombocytopenia

Immune thrombocytopenia (ITP) is an auto-immune condition characterised by low blood platelet count (thrombocytopenia) and is associated with an increase risk in bleeding which often presents as bruising or petechia/purpura.

Miller-Fisher Syndrome

Miller-Fisher syndrome is a variation of Guillain-Barré Syndrome that affects the nervous system and can cause weakness in the face and a lack of balance and co-ordination. Similar to Guillain-Barré Syndrome, this syndrome has been associated with viral infections such as the flu.

Miscarriage

The loss of a pregnancy during the first 23 weeks.

Myocarditis

Myocarditis is the inflammation of the heart muscle (myocardium).

Non-clinical studies

Non-clinical studies refer to studies that are not performed on the human body. These are largely done before clinical trials in humans and can include animal safety and efficacy studies, human tissue sample studies or toxicology.

Pericarditis

Pericarditis is inflammation of the pericardium, the protective sac that surrounds your heart.

Regulation 174 authorisation

Temporary authorisation for supply of a medicine or vaccine by the UK Department of Health and Social Care and the Medicines and Healthcare products Regulatory Agency. This temporary authorisation grants permission for a medicine (vaccine) to be used for active immunisation to prevent COVID-19 disease caused by SARS-CoV-2 virus. Authorisation is subject to a number of conditions. These are available for each vaccine on the MHRA website.

Suspected adverse reactions

Also known as side effects. All medicines or vaccines can cause adverse reactions in some people. Adverse drug reactions reported to the MHRA are looked at and used to assess the balance of risks and benefits of medicines and vaccines.

Stillbirth

A stillbirth is when a baby is born dead after 24 completed weeks of pregnancy. If the baby dies before 24 completed weeks, it's known as a miscarriage.

Temporal Association

Events occurring following vaccination but may or may not be caused by the vaccine.

Third dose/vaccination

A COVID-19 third vaccine is being offered to those who had a weakened immune system when they had the first two doses of the COVID-19 vaccination. The third dose may help to improve immune response and give better protection.

Thrombocytopenia

Thrombocytopenia is where the blood contains a lower than normal number of platelets. Platelets are the smallest of the blood cells and are involved in the clotting process.

Transverse Myelitis

Transverse myelitis is a rare acute neurological disorder causing inflammation of the spinal cord, the part of the central nervous system that sends impulses from the brain to nerves in the body.

Yellow Card scheme

The MHRA's scheme for healthcare professionals and members of the public to report suspected adverse reactions for a medicine or vaccine, as well as medical devices and other products. The dedicated Coronavirus Yellow Card reporting site was launched in May 2020 specifically for medicines and medical devices used in COVID-19, as well as COVID-19 vaccines when authorised.

COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

All UK spontaneous reports received between 9/12/20 and 18/05/22 for mRNA Pfizer/BioNTech vaccine.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Blood disorders		
Anaemia deficiencies		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	7	0
Deficiency anaemia	1	0
Iron deficiency anaemia	8	0
Pernicious anaemia	2	0
Anaemias NEC		
Anaemia	149	0
Anaemia macrocytic	2	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	3	0
Blood loss anaemia	1	0
Microcytic anaemia	1	0
Normocytic anaemia	1	0
Anaemias haemolytic NEC		
Coombs negative haemolytic anaemia	1	0
Haemolytic anaemia	7	0
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	19	0
Cold type haemolytic anaemia	1	0
Evans syndrome	1	0
Warm autoimmune haemolytic anaemia	1	0
Anaemias haemolytic mechanical factor		
Microangiopathic haemolytic anaemia	1	0
Bleeding tendencies		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	55	0
Spontaneous haematoma	2	0
Coagulation factor deficiencies		
Acquired factor VIII deficiency	1	0
Acquired haemophilia	4	0
Coagulopathies		
Abnormal clotting factor	4	0
Antiphospholipid syndrome	6	0
Coagulopathy	31	1
Disseminated intravascular coagulation	3	0
Hypercoagulation	4	0
Thrombotic microangiopathy	4	0
Eosinophilic disorders		
Eosinophilia	12	0
Haematological disorders		
Blood disorder	7	0
Bone marrow disorder	1	0
Bone marrow oedema	1	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	14	0
Methaemoglobinaemia	1	0
Haemolyses NEC		
Haemolysis	6	0
Intravascular haemolysis	1	0
Jaundice acholuric	1	0
Leukocytoses NEC		

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Leukocytosis	3	0
Lymphocytic infiltration	1	0
Lymphocytosis	6	0
Neutrophilia	12	0
Leukopenias NEC		
Leukopenia	4	1
Lymphopenia	4	0
Lymphatic system disorders NEC		
Abdominal lymphadenopathy	4	0
Hilar lymphadenopathy	3	0
Lymph node pain	2281	0
Lymph node ulcer	1	0
Lymphadenitis	191	0
Lymphadenopathy	13769	0
Lymphadenopathy mediastinal	1	0
Lymphatic disorder	3	0
Lymphatic insufficiency	1	0
Lymphoid tissue hyperplasia	1	0
Necrotic lymphadenopathy	4	0
Pseudolymphoma	12	0
Retroperitoneal lymphadenopathy	1	0
Marrow depression and hypoplastic anaemias		
Aplasia pure red cell	2	0
Aplastic anaemia	1	1
Hypoplastic anaemia	2	0
Myelosuppression	1	0
Pancytopenia	9	0
Neutropenias		
Autoimmune neutropenia	2	0
Neutropenia	44	0
Platelet disorders NEC		
Platelet anisocytosis	1	0
Platelet disorder	4	0
Polycythaemia (excl rubra vera)		
Polycythaemia	3	0
Purpuras (excl thrombocytopenic)		
Purpura non-thrombocytopenic	1	0
Red blood cell abnormal findings NEC		
Macrocytosis	2	0
Polychromasia	2	0
Red blood cell abnormality	2	0
Spleen disorders		
Spleen atrophy	1	0
Splenic infarction	4	0
Splenic lesion	1	0
Splenic thrombosis	2	0
Splenic vein thrombosis	2	0
Splenomegaly	12	0
Thrombocytopenias		
Acquired amegakaryocytic thrombocytopenia	1	0
Immune thrombocytopenia	87	0
Thrombocytopenia	243	1
Thrombocytopenic purpura	9	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022
Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968
MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Thrombotic thrombocytopenic purpura	7	0
Thrombocytoses		
Thrombocytosis	7	0
Blood disorders SOC TOTAL	**17123**	**4**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Cardiac disorders		
Aortic valvular disorders		
Aortic valve incompetence	2	0
Cardiac conduction disorders		
Atrioventricular block	34	1
Atrioventricular block complete	3	1
Atrioventricular block first degree	3	0
Atrioventricular block second degree	5	0
Bundle branch block	2	0
Bundle branch block left	6	0
Bundle branch block right	5	0
Trifascicular block	1	0
Cardiac disorders NEC		
Acute cardiac event	7	0
Atrial thrombosis	1	0
Cardiac disorder	105	3
Cardiac dysfunction	2	0
Cardiac ventricular thrombosis	2	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	9	0
Intracardiac thrombus	7	0
Cardiac hypertensive complications		
Hypertensive heart disease	3	2
Cardiac infections and inflammations NEC		
Carditis	10	0
Cardiac neoplasms NEC		
Pericardial cyst	1	0
Cardiac signs and symptoms NEC		
Cardiac discomfort	39	0
Cardiovascular symptom	4	0
Palpitations	6253	1
Cardiac valve disorders NEC		
Cardiac valve disease	4	0
Heart valve incompetence	3	0
Cardiomyopathies		
Cardiomyopathy	17	1
Congestive cardiomyopathy	9	0
Stress cardiomyopathy	3	0
Coronary artery disorders NEC		
Arteriosclerosis coronary artery	2	0
Coronary artery disease	10	3
Coronary artery dissection	1	0
Coronary artery occlusion	4	0
Coronary artery thrombosis	8	2
Endocarditis NEC		
Endocarditis noninfective	1	1
Heart failures NEC		
Cardiac failure	87	10
Cardiac failure acute	9	2
Cardiac failure chronic	2	0
Cardiac failure congestive	7	4
Cardiogenic shock	6	2
Cardiopulmonary failure	2	1
Ischaemic coronary artery disorders		

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Acute coronary syndrome	10	1
Acute myocardial infarction	30	4
Angina pectoris	343	1
Angina unstable	5	0
Arteriospasm coronary	4	0
Microvascular coronary artery disease	3	0
Myocardial infarction	301	43
Myocardial ischaemia	12	7
Left ventricular failures		
Acute left ventricular failure	2	2
Left ventricular failure	7	2
Mitral valvular disorders		
Mitral valve incompetence	8	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiac aneurysm	1	1
Cardiac ventricular scarring	1	0
Cardiomegaly	56	3
Dilatation ventricular	1	0
Left atrial dilatation	1	0
Left ventricular dysfunction	19	0
Left ventricular enlargement	3	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	8	0
Myocardial haemorrhage	1	0
Myocardial injury	26	0
Myocardial necrosis	1	0
Myocardial oedema	7	0
Myocardial rupture	1	0
Right atrial enlargement	1	0
Right ventricular dilatation	1	0
Right ventricular dysfunction	2	0
Right ventricular enlargement	1	0
Systolic dysfunction	1	0
Ventricular dysfunction	2	0
Ventricular hypertrophy	1	0
Ventricular hypokinesia	4	0
Noninfectious myocarditis		
Eosinophilic myocarditis	1	0
Hypersensitivity myocarditis	1	0
Myocarditis	698	3
Myocarditis post infection	1	0
Myopericarditis	93	0
Noninfectious pericarditis		
Pericarditis	537	2
Pericarditis constrictive	1	0
Pericarditis lupus	1	0
Pleuropericarditis	1	0
Pericardial disorders NEC		
Cardiac tamponade	2	1
Pericardial effusion	51	2
Pericardial fibrosis	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Pericardial haemorrhage	4	3
Pericardial rub	2	0
Rate and rhythm disorders NEC		
Arrhythmia	192	1
Arrhythmia neonatal	1	0
Bradycardia	79	0
Bradycardia foetal	2	0
Cardiac flutter	625	0
Extrasystoles	223	0
Heart alternation	3	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	47	0
Tachyarrhythmia	11	0
Tachycardia	2497	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	1	0
Right ventricular failures		
Cor pulmonale	1	0
Right ventricular failure	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	16	0
Atrial fibrillation	294	1
Atrial flutter	46	0
Atrial tachycardia	12	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	9	0
Sinus bradycardia	15	0
Sinus node dysfunction	1	0
Sinus tachycardia	87	0
Supraventricular extrasystoles	6	0
Supraventricular tachycardia	51	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	6	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	130	45
Cardio-respiratory arrest	1	1
Pulseless electrical activity	7	0
Ventricular arrhythmia	6	0
Ventricular extrasystoles	32	0
Ventricular fibrillation	10	1
Ventricular tachycardia	17	0
Cardiac disorders SOC TOTAL	**13375**	**158**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Congenital disorders		
Autosomal chromosomal abnormalities		
Trisomy 8	1	0
Cardiac disorders congenital NEC		
Heart disease congenital	20	0
Cardiac hypoplasias congenital		
Ventricular hypoplasia	1	0
Cardiac septal defects congenital		
Atrial septal defect	2	0
Hypertrophic cardiomyopathy	1	0
Ventricular septal defect	1	0
Cardiac valve disorders congenital		
Bicuspid aortic valve	3	0
Central nervous system disorders congenital NEC		
Spina bifida	2	1
Syringomyelia	1	0
Cerebellar disorders congenital		
Arnold-Chiari malformation	1	0
Hereditary ataxia	2	0
Cerebral disorders congenital		
Anencephaly	2	0
Cerebral palsy	4	0
Congenital hydrocephalus	1	0
Chromosomal abnormalities NEC		
Cytogenetic abnormality	1	0
Coagulation disorders congenital		
Factor IX deficiency	1	0
Haemophilia	2	0
Congenital disorders NEC		
Congenital anomaly	1	0
Foetal malformation	1	0
Heterotaxia	1	0
Connective tissue disorders congenital		
Ehlers-Danlos syndrome	5	0
Diaphragmatic disorders congenital		
Congenital diaphragmatic hernia	1	0
Gastrointestinal tract disorders congenital NEC		
Gastroschisis	3	0
Genetic polymorphisms		
Genetic polymorphism	1	0
Great vessel disorders congenital		
Congenital great vessel anomaly	1	0
Transposition of the great vessels	1	0
Haematological disorders congenital NEC		
Amegakaryocytic thrombocytopenia	1	0
Neonatal alloimmune thrombocytopenia	1	0
Haemoglobinopathies congenital		
Congenital methaemoglobinaemia	1	0
Immune system abnormalities congenital		
Combined immunodeficiency	1	0
Inborn errors of lipid metabolism		
Short-chain acyl-coenzyme A dehydrogenase deficiency	1	0
Inborn errors of metabolism NEC		
Alpha-1 antitrypsin deficiency	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Inborn errors of porphyrin metabolism		
Porphyria	1	0
Lymphatic system disorders congenital		
Cystic lymphangioma	3	0
Male reproductive tract disorders congenital		
Cryptorchism	1	0
Micropenis	4	0
Penoscrotal fusion	1	0
Phimosis	1	0
Musculoskeletal and connective tissue disorders of limbs congenital		
Congenital musculoskeletal disorder of limbs	1	0
Developmental hip dysplasia	1	0
Musculoskeletal and connective tissue disorders of skull congenital		
Platybasia	1	0
Musculoskeletal and connective tissue disorders of spine congenital		
Block vertebra	1	0
Brachyolmia	1	0
Neurological disorders congenital NEC		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Neurofibromatosis	1	0
Tourette's disorder	4	0
Ocular disorders congenital NEC		
Colour blindness	4	0
Congenital eye disorder	1	0
Palate disorders congenital		
Cleft lip and palate	2	0
Peripheral nervous system disorders congenital NEC		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
Pulmonary and bronchial disorders congenital		
Congenital cystic lung	1	0
Retinal disorders congenital		
Retinitis pigmentosa	1	0
Sex chromosomal abnormalities		
Turner's syndrome	1	0
Skin and subcutaneous tissue disorders congenital NEC		
Acral peeling skin syndrome	1	0
Tongue disorders congenital		
Ankyloglossia congenital	1	0
Vascular anomalies congenital NEC		
Congenital LUMBAR syndrome	1	0
Venous disorders congenital		
Anomalous pulmonary venous connection	1	0
Congenital disorders SOC TOTAL	**108**	**1**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear canal erythema	1	0
Ear congestion	39	0
Ear discomfort	107	0
Ear disorder	23	0
Ear haemorrhage	15	0
Ear inflammation	2	0
Ear pain	1185	0
Ear pruritus	12	0
Ear swelling	39	0
Otorrhoea	8	0
Ototoxicity	1	0
Paraesthesia ear	1	0
Eustachian tube disorders		
Eustachian tube disorder	5	0
Eustachian tube dysfunction	11	0
Eustachian tube obstruction	7	0
External ear disorders NEC		
Auricular swelling	2	0
Excessive cerumen production	12	0
External ear pain	6	0
Red ear syndrome	2	0
External ear infections and inflammations		
Chondrodermatitis nodularis chronica helicis	1	0
External ear inflammation	2	0
Hearing disorders NEC		
Auditory disorder	6	0
Diplacusis	2	0
Dysacusis	1	0
Hearing losses		
Conductive deafness	1	0
Deafness	306	0
Deafness bilateral	12	0
Deafness neurosensory	27	0
Deafness transitory	10	0
Deafness unilateral	40	0
Hypoacusis	233	0
Mixed deafness	1	0
Sudden hearing loss	52	0
Hyperacusia		
Hyperacusis	79	0
Misophonia	3	0
Inner ear disorders NEC		
Acute vestibular syndrome	2	0
Inner ear disorder	13	0
Meniere's disease	16	0
Vestibular disorder	15	0
Inner ear infections and inflammations		
Autoimmune inner ear disease	1	0
Inner ear inflammation	11	0
Inner ear signs and symptoms		
Motion sickness	70	0
Phobic postural vertigo	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
Tinnitus	2539	0
Vertigo	1677	0
Vertigo labyrinthine	13	0
Vertigo positional	88	0
Mastoid disorders		
Mastoid effusion	1	0
Middle ear disorders NEC		
Middle ear disorder	3	0
Middle ear effusion	1	0
Middle ear infections and inflammations		
Middle ear inflammation	1	0
Tympanic membrane disorders (excl infections)		
Tympanic membrane perforation	4	0
Ear disorders SOC TOTAL	**6710**	**0**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Endocrine disorders		
Acute and chronic thyroiditis		
Autoimmune thyroiditis	4	0
Thyroiditis	24	0
Thyroiditis acute	4	0
Thyroiditis subacute	9	0
Adrenal cortical hypofunctions		
Addison's disease	3	0
Adrenal insufficiency	3	0
Adrenocortical insufficiency acute	16	0
Adrenal gland disorders NEC		
Adrenal disorder	3	0
Adrenal haemorrhage	3	0
Adrenal mass	1	0
Anterior pituitary hyperfunction		
Pituitary-dependent Cushing's syndrome	1	0
Anterior pituitary hypofunction		
Hypopituitarism	2	0
Luteal phase deficiency	1	0
Endocrine abnormalities of gonadal function NEC		
Oestrogen deficiency	1	0
Endocrine abnormalities of puberty		
Delayed menarche	5	0
Premature menarche	21	0
Female gonadal function disorders		
Anovulatory cycle	68	0
Ovulation delayed	35	0
Male gonadal function disorders		
Androgen deficiency	1	0
Thyroid disorders NEC		
Autoimmune thyroid disorder	1	0
Goitre	18	0
Thyroid disorder	15	0
Thyroid mass	2	0
Thyroid pain	12	0
Thyroid hyperfunction disorders		
Basedow's disease	14	0
Hyperthyroidism	59	0
Primary hyperthyroidism	1	0
Thyrotoxic crisis	6	0
Thyroid hypofunction disorders		
Autoimmune hypothyroidism	1	0
Hypothyroidic goitre	1	0
Hypothyroidism	47	0
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
Thyroid neoplasms		
Thyroid cyst	1	0
Endocrine disorders SOC TOTAL	385	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Eye disorders		
Amblyopic vision impairment		
Amblyopia	7	0
Anterior chamber bleeding and vascular disorders		
Spontaneous hyphaema	1	0
Cataract conditions		
Cataract	17	0
Choroid and vitreous haemorrhages and vascular disorders		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	4	0
Choroid and vitreous structural change, deposit and degeneration		
Vitreous detachment	21	0
Vitreous floaters	122	0
Colour blindness (incl acquired)		
Colour blindness acquired	2	0
Dyschromatopsia	15	0
Conjunctival and corneal bleeding and vascular disorders		
Conjunctival haemorrhage	52	0
Scleral haemorrhage	1	0
Conjunctival infections, irritations and inflammations		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
Conjunctival ulcer	1	0
Conjunctivitis allergic	3	0
Corneal infections, oedemas and inflammations		
Corneal oedema	3	0
Keratitis	7	0
Ulcerative keratitis	6	0
Corneal structural change, deposit and degeneration		
Corneal scar	1	0
Eyelid movement disorders		
Blepharospasm	172	0
Excessive eye blinking	6	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	52	0
Paralytic lagophthalmos	2	0
Glaucomas (excl congenital)		
Angle closure glaucoma	2	0
Glaucoma	8	0
Ocular hypertension	1	0
Iris and ciliary body structural change, deposit and degeneration		
Eye colour change	3	0
Iris and uveal tract infections, irritations and inflammations		
Autoimmune uveitis	3	0
Iridocyclitis	21	0
Iritis	13	0
Uveitis	57	0
Vogt-Koyanagi-Harada disease	1	0
Lacrimation disorders		
Dry eye	179	0
Lacrimation decreased	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Lacrimation increased	169	0
Lid bleeding and vascular disorders		
Eyelid bleeding	1	0
Lid, lash and lacrimal infections, irritations and inflammations		
Blepharitis	20	0
Blepharitis allergic	1	0
Chalazion	7	0
Eczema eyelids	11	0
Erythema of eyelid	11	0
Eyelid cyst	7	0
Eyelid irritation	4	0
Eyelid margin crusting	5	0
Eyelid oedema	15	0
Eyelid rash	20	0
Meibomian gland dysfunction	1	0
Swelling of eyelid	148	0
Swollen tear duct	2	0
Lid, lash and lacrimal structural disorders		
Dacryostenosis acquired	2	0
Dermatochalasis	1	0
Ectropion	1	0
Eyelash changes	1	0
Eyelid exfoliation	3	0
Eyelid skin dryness	2	0
Eyelid thickening	1	0
Floppy eyelid syndrome	1	0
Growth of eyelashes	3	0
Lacrimal gland enlargement	1	0
Lagophthalmos	4	0
Ocular bleeding and vascular disorders NEC		
Eye haematoma	4	0
Eye haemorrhage	39	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	1	0
Ocular disorders NEC		
Dark circles under eyes	10	0
Eye disorder	44	0
Eye oedema	19	0
Eye pain	1311	0
Eye swelling	662	0
Eye symptom	10	0
Eye ulcer	6	0
Eyelid disorder	17	0
Eyelid pain	16	0
Eyelids pruritus	8	0
Ocular discomfort	35	0
Periorbital oedema	21	0
Periorbital pain	5	0
Periorbital swelling	134	0
Retinal disorder	2	0
Vitreous disorder	1	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	22	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eye discharge	34	0
Eye inflammation	40	0
Eye irritation	107	0
Eye pruritus	286	0
Limbal swelling	4	0
Ocular hyperaemia	270	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Eye movement disorder	44	0
Gaze palsy	3	0
Ocular myasthenia	1	0
Ophthalmoplegia	8	0
Strabismus	10	0
Ocular sensation disorders		
Abnormal sensation in eye	24	0
Asthenopia	175	0
Eye paraesthesia	2	0
Eyelid sensory disorder	3	0
Foreign body sensation in eyes	19	0
Hypoaesthesia eye	18	0
Photophobia	529	0
Optic disc abnormalities NEC		
Papilloedema	8	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	4	0
Orbital infections, inflammations and irritations		
Parophthalmia	1	0
Orbital structural change, deposit and degeneration		
Orbital oedema	2	0
Pupil disorders		
Anisocoria	15	0
Miosis	2	0
Mydriasis	24	0
Pupil fixed	4	0
Pupillary disorder	1	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Altered visual depth perception	5	0
Astigmatism	3	0
Hypermetropia	4	0
Myopia	4	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Papillophlebitis	1	0
Retinal artery occlusion	18	0
Retinal artery thrombosis	2	0
Retinal haemorrhage	12	0
Retinal ischaemia	1	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	48	0
Retinal vein thrombosis	2	0
Retinal structural change, deposit and degeneration		

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Age-related macular degeneration	1	0
Chorioretinal disorder	1	0
Epiretinal membrane	1	0
Macular degeneration	4	0
Macular hole	3	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	3	0
Retinal degeneration	1	0
Retinal detachment	8	0
Retinal tear	3	0
Retinal toxicity	3	0
Retinal, choroid and vitreous infections and inflammations		
Birdshot chorioretinopathy	2	0
Choroiditis	1	0
Cystoid macular oedema	1	0
Macular oedema	7	0
Retinal oedema	2	0
Retinal vasculitis	3	0
Retinopathies NEC		
Acute macular neuroretinopathy	3	0
Central serous chorioretinopathy	8	0
Retinal exudates	3	0
Retinopathy	4	0
Scleral infections, irritations and inflammations		
Episcleritis	9	0
Scleritis	6	0
Scleral structural change, deposit and degeneration		
Scleral discolouration	2	0
Structural change, deposit and degeneration of eye NEC		
Endocrine ophthalmopathy	2	0
Exophthalmos	4	0
Visual colour distortions		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	5	0
Erythropsia	2	0
Xanthopsia	1	0
Visual disorders NEC		
Charles Bonnet syndrome	2	0
Diplopia	191	0
Dysmetropsia	1	0
Glare	1	0
Halo vision	10	0
Heteronymous diplopia	1	0
Metamorphopsia	25	0
Oscillopsia	3	0
Photopsia	169	0
Scintillating scotoma	4	0
Vision blurred	1466	0
Visual brightness	3	0
Visual snow syndrome	8	0
Visual field disorders		

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

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Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Visual field defect	42	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	4	0
Blindness	168	0
Blindness cortical	1	0
Blindness transient	22	0
Blindness unilateral	20	0
Central vision loss	6	0
Sudden visual loss	5	0
Visual acuity reduced	30	0
Visual acuity reduced transiently	1	0
Visual impairment	476	0
Visual pathway disorders		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	**8111**	**0**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Abdominal findings abnormal		
Abdominal mass	2	0
Gastrointestinal sounds abnormal	18	0
Abdominal hernias NEC		
Abdominal hernia	2	0
Abdominal wall conditions NEC		
Abdominal wall haematoma	2	0
Acute and chronic pancreatitis		
Alcoholic pancreatitis	1	0
Autoimmune pancreatitis	1	0
Obstructive pancreatitis	1	0
Pancreatitis	19	0
Pancreatitis acute	17	1
Pancreatitis chronic	1	0
Pancreatitis necrotising	2	0
Anal and rectal disorders NEC		
Anal fissure	2	0
Anal sphincter atony	1	0
Rectal prolapse	1	0
Anal and rectal pains		
Proctalgia	15	0
Anal and rectal signs and symptoms		
Anal blister	1	0
Anal eczema	1	0
Anal erythema	1	0
Anal hypoaesthesia	2	0
Anal pruritus	2	0
Anal rash	1	0
Anal spasm	1	0
Anorectal discomfort	5	0
Anorectal swelling	1	0
Rectal discharge	2	0
Rectal spasm	1	0
Rectal tenesmus	1	0
Anal and rectal ulcers and perforation		
Anal ulcer	1	0
Benign oral cavity neoplasms		
Mouth cyst	6	0
Tongue cyst	4	0
Tongue polyp	2	0
Colitis (excl infective)		
Autoimmune colitis	2	0
Colitis	60	1
Colitis ischaemic	1	0
Colitis microscopic	3	0
Colitis ulcerative	84	0
Crohn's disease	52	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	12	0
Dental and periodontal infections and inflammations		
Dental caries	2	0
Periodontal inflammation	1	0
Dental developmental disorders and anomalies		

Case Series Drug Analysis Print

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Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Tooth impacted	1	0
Dental disorders NEC		
Loose tooth	5	0
Malpositioned teeth	2	0
Periodontal disease	1	0
Teeth brittle	3	0
Teething	9	0
Tooth disorder	2	0
Tooth erosion	1	0
Tooth socket haemorrhage	1	0
Dental pain and sensation disorders		
Dental discomfort	7	0
Dental paraesthesia	14	0
Hyperaesthesia teeth	39	0
Toothache	197	0
Dental surface disorders		
Tooth discolouration	10	0
Diaphragmatic hernias		
Hiatus hernia	8	0
Diarrhoea (excl infective)		
Diarrhoea	6148	0
Diarrhoea haemorrhagic	27	0
Diverticula		
Diverticulum	7	0
Diverticulum intestinal	1	0
Duodenal and small intestinal stenosis and obstruction		
Small intestinal obstruction	4	0
Duodenal ulcers and perforation		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
Dyspeptic signs and symptoms		
Dyspepsia	549	0
Epigastric discomfort	15	0
Eructation	64	0
Faecal abnormalities NEC		
Abnormal faeces	23	0
Faecaloma	7	0
Faeces discoloured	63	0
Faeces hard	2	0
Faeces pale	5	0
Faeces soft	13	0
Mucous stools	12	0
Flatulence, bloating and distension		
Abdominal distension	607	0
Aerophagia	3	0
Flatulence	203	0
Gastric and oesophageal haemorrhages		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
Gastric ulcers and perforation		
Gastric ulcer	7	0
Gastritis (excl infective)		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Chronic gastritis	4	0
Gastritis	72	0
Reflux gastritis	8	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal migraine	2	0
Abdominal pain	1714	0
Abdominal pain lower	154	0
Abdominal pain upper	2834	0
Abdominal rigidity	27	0
Abdominal tenderness	15	0
Gastrointestinal pain	170	0
Oesophageal pain	14	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	280	0
Duodenogastric reflux	4	0
Gastric dilatation	8	0
Gastrooesophageal reflux disease	197	0
Impaired gastric emptying	10	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
Gastrointestinal disorders NEC		
Appendicolith	1	0
Appendix disorder	2	0
Food poisoning	7	0
Functional gastrointestinal disorder	11	0
Gastric disorder	10	0
Gastrointestinal disorder	31	0
Stomach mass	4	0
Gastrointestinal dyskinetic disorders		
Bowel movement irregularity	9	0
Change of bowel habit	14	0
Dyschezia	4	0
Gastrointestinal motility disorder	5	0
Oesophageal achalasia	1	0
Gastrointestinal fistulae		
Diverticular fistula	2	0
Gastrointestinal inflammatory disorders NEC		
Appendicitis noninfective	1	0
Duodenitis	1	0
Enteritis	6	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	5	0
Gastrointestinal tract irritation	1	0
Intestinal angioedema	2	0
Gastrointestinal mucosal dystrophies and secretion disorders		
Barrett's oesophagus	2	0
Hyperchlorhydria	4	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	712	0
Abdominal symptom	2	0
Acute abdomen	8	0
Anal incontinence	22	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Gastrointestinal disorders (Gastrointestinal disorders cont'd)		
Breath odour	22	0
Dysphagia	247	1
Gastrointestinal wall thickening	1	0
Malignant dysphagia	1	0
Odynophagia	48	0
Gastrointestinal spastic and hypermotility disorders		
Cardiospasm	1	0
Defaecation urgency	12	0
Frequent bowel movements	35	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	106	0
Oesophageal spasm	5	0
Pylorospasm	1	0
Gastrointestinal stenosis and obstruction NEC		
Ileus	2	0
Intestinal obstruction	8	0
Neonatal intestinal obstruction	1	0
Volvulus	1	0
Gastrointestinal vascular malformations		
Gastric antral vascular ectasia	11	0
Gastrointestinal vascular occlusion and infarction		
Intestinal infarction	1	1
Intestinal ischaemia	10	2
Mesenteric vein thrombosis	10	0
Omental infarction	1	0
Thrombosis mesenteric vessel	2	0
Visceral venous thrombosis	1	0
Gingival disorders, signs and symptoms NEC		
Gingival blister	13	0
Gingival discomfort	8	0
Gingival disorder	5	0
Gingival erythema	2	0
Gingival hypertrophy	1	0
Gingival oedema	2	0
Gingival pain	138	0
Gingival pruritus	2	0
Gingival recession	1	0
Gingival swelling	43	0
Gingival ulceration	3	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	14	0
Gingival haemorrhages		
Gingival bleeding	85	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Gastric varices	1	0
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	35	1
Haemorrhoids thrombosed	1	0
Inguinal hernias		
Inguinal hernia	1	0
Intestinal haemorrhages		
Anal haemorrhage	23	1
Intestinal haemorrhage	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Rectal haemorrhage	84	0
Small intestinal haemorrhage	5	0
Intestinal ulcers and perforation NEC		
Intestinal perforation	6	2
Large intestinal ulcer	1	0
Large intestinal ulcer haemorrhage	1	0
Large intestine perforation	1	0
Large intestinal stenosis and obstruction		
Large intestinal obstruction	2	2
Malabsorption syndromes		
Bile acid malabsorption	5	0
Coeliac disease	14	0
Malabsorption	1	0
Steatorrhoea	4	0
Nausea and vomiting symptoms		
Cyclic vomiting syndrome	1	0
Discoloured vomit	13	0
Infantile vomiting	7	0
Nausea	15421	0
Regurgitation	1	0
Retching	117	0
Vomiting	5276	1
Vomiting projectile	76	0
Non-mechanical ileus		
Ileus paralytic	2	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	19	1
Haematemesis	42	2
Haematochezia	61	0
Melaena	11	0
Upper gastrointestinal haemorrhage	14	1
Oesophageal disorders NEC		
Oesophageal disorder	1	0
Oesophageal stenosis and obstruction		
Oesophageal stenosis	3	0
Oesophagitis (excl infective)		
Eosinophilic oesophagitis	2	0
Oesophagitis	6	0
Oral dryness and saliva altered		
Aptyalism	5	0
Dry mouth	550	0
Lip dry	50	0
Saliva altered	8	0
Salivary hypersecretion	55	0
Oral soft tissue disorders NEC		
Angina bullosa haemorrhagica	1	0
Chapped lips	29	0
Cheilitis	32	0
Enlarged uvula	15	0
Leukoplakia oral	2	0
Lip blister	36	0
Lip disorder	7	0
Oral disorder	23	0

Case Series Drug Analysis Print

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Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Oral lichen planus	17	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	7	0
Oral soft tissue haemorrhages		
Lip haemorrhage	2	0
Mouth haemorrhage	23	0
Oral blood blister	19	0
Oral purpura	2	0
Oral soft tissue infections		
Angular cheilitis	4	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	3	0
Burning mouth syndrome	7	0
Coating in mouth	1	0
Hypoaesthesia oral	521	0
Lip discolouration	11	0
Lip erythema	4	0
Lip exfoliation	6	0
Lip pain	67	0
Lip pruritus	18	0
Lip scab	1	0
Oral discomfort	91	0
Oral dysaesthesia	1	0
Oral mucosal blistering	18	0
Oral mucosal discolouration	2	0
Oral mucosal eruption	21	0
Oral mucosal erythema	9	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral mucosal scab	2	0
Oral pain	191	0
Oral pruritus	24	0
Paraesthesia oral	976	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	4	0
Lip swelling	904	0
Mouth swelling	120	0
Oedema mouth	4	0
Palatal oedema	4	0
Palatal swelling	5	0
Pancreatic disorders NEC		
Pancreatic disorder	3	0
Pancreatic failure	1	0
Pancreatic mass	1	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	14	0
Peritoneal and retroperitoneal disorders		
Ascites	3	0
Peritoneal disorder	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Abdominal adhesions	2	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0
Retroperitoneal haematoma	1	0
Retroperitoneal haemorrhage	2	1
Rectal inflammations NEC		
Proctitis	4	0
Proctitis ulcerative	1	0
Salivary gland disorders NEC		
Salivary gland disorder	1	0
Salivary gland mucocoele	1	0
Salivary gland pain	13	0
Salivary gland enlargements		
Parotid gland enlargement	12	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	7	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	2	0
Stomatitis and ulceration		
Aphthous ulcer	60	0
Lip ulceration	23	0
Mouth ulceration	495	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	69	0
Tongue disorders		
Glossitis	23	0
Hypertrophy of tongue papillae	2	0
Plicated tongue	4	0
Tongue disorder	45	0
Tongue geographic	8	0
Tongue haemorrhage	3	0
Tongue ulceration	34	0
Trichoglossia	4	0
Tongue signs and symptoms		
Glossodynia	233	0
Scalloped tongue	5	0
Stiff tongue	4	0
Swollen tongue	560	0
Tongue blistering	19	0
Tongue coated	20	0
Tongue discolouration	40	0
Tongue discomfort	48	0
Tongue dry	17	0
Tongue eruption	11	0
Tongue erythema	13	0
Tongue exfoliation	2	0
Tongue movement disturbance	8	0
Tongue oedema	24	0
Tongue pruritus	2	0
Tongue rough	5	0
Tongue spasm	12	0
Tooth missing		

Case Series Drug Analysis Print

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Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968
MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Tooth loss	6	0
Gastrointestinal disorders SOC TOTAL	**42695**	**19**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site bruise	9	0
Administration site erythema	4	0
Administration site extravasation	3	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	2	0
Administration site joint movement impairment	2	0
Administration site joint pain	1	0
Administration site nerve damage	1	0
Administration site pain	21	0
Administration site rash	5	0
Administration site reaction	1	0
Administration site swelling	5	0
Administration site urticaria	2	0
Administration site warmth	2	0
Puncture site bruise	43	0
Puncture site pain	9	0
Puncture site reaction	1	0
Puncture site swelling	2	0
Vessel puncture site bruise	2	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
Adverse effect absent		
No adverse event	9	0
Application and instillation site reactions		
Application site acne	2	0
Application site bruise	12	0
Application site burn	1	0
Application site dryness	2	0
Application site erythema	18	0
Application site haemorrhage	1	0
Application site hypoaesthesia	2	0
Application site irritation	1	0
Application site joint erythema	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	2	0
Application site pain	12	0
Application site pruritus	4	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	7	0
Application site warmth	1	0
Instillation site warmth	9	0
Asthenic conditions		
Asthenia	2444	1
Chronic fatigue syndrome	88	0
Decreased activity	10	0
Fatigue	26311	1
Malaise	5963	1

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Sluggishness	19	0
Body temperature altered		
Hyperthermia	7	0
Hyperthermia malignant	1	0
Hypothermia	27	0
Temperature regulation disorder	15	0
Breast complications associated with device		
Breast implant palpable	1	0
Capsular contracture associated with breast implant	2	0
Cardiac complications associated with device		
Prosthetic cardiac valve thrombosis	2	0
Complications associated with device NEC		
Capsular contracture associated with implant	1	0
Complication of device removal	3	0
Injury associated with device	5	0
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	2	0
Death and sudden death		
Brain death	4	3
Cardiac death	3	2
Clinical death	1	1
Death	196	196
Sudden cardiac death	1	1
Sudden death	28	28
Febrile disorders		
Hyperpyrexia	10	0
Pyrexia	17019	0
Feelings and sensations NEC		
Chills	10568	0
Feeling abnormal	1861	0
Feeling cold	1382	0
Feeling drunk	83	0
Feeling hot	1315	0
Feeling jittery	34	0
Feeling of body temperature change	371	0
Feeling of relaxation	3	0
Hangover	85	0
Hunger	51	0
Sensation of blood flow	5	0
Sensation of foreign body	64	0
Sense of oppression	1	0
Temperature intolerance	56	0
Thirst	384	0
Thirst decreased	2	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait deviation	1	0
Gait disturbance	295	0
Gait inability	117	0
Loss of control of legs	29	0
General signs and symptoms NEC		

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Adhesion	2	0
Chronic disease	1	0
Concomitant disease progression	1	1
Condition aggravated	363	0
Crepitations	5	0
Crying	169	0
Deformity	2	0
Developmental delay	1	0
Discharge	12	0
Disease progression	2	0
Disease recurrence	32	0
Effusion	3	0
Energy increased	27	0
Exercise tolerance decreased	46	0
Exercise tolerance increased	2	0
Fat tissue increased	1	0
Foaming at mouth	3	0
General physical health deterioration	18	3
General symptom	3	0
Glassy eyes	8	0
High-pitched crying	3	0
Illness	2294	0
Induration	18	0
Influenza like illness	2706	0
Irritability postvaccinal	2	0
Local reaction	93	0
Moaning	4	0
Multiple organ dysfunction syndrome	14	6
Nonspecific reaction	2	0
Organ failure	4	2
Perforation	2	0
Peripheral swelling	4466	0
Physical deconditioning	2	0
Pre-existing condition improved	9	0
Prolapse	1	0
Screaming	24	0
Secretion discharge	27	0
Stenosis	1	0
Swelling	3600	0
Swelling face	990	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
Tissue rupture	1	0
Unevaluable event	1	0
Healing abnormal NEC		
Impaired healing	7	0
Implant and catheter site reactions		
Implant site discolouration	2	0
Implant site pain	3	0
Implant site rash	1	0
Implant site reaction	1	0
Implant site swelling	2	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Implant site urticaria	1	0
Implant site warmth	3	0
Inflammations		
Chronic inflammatory response syndrome	1	0
Foreign body reaction	1	0
Granuloma	1	0
Inflammation	663	0
Papillitis	1	0
Scar inflammation	3	0
Serositis	1	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	6	0
Infusion site reactions		
Infusion site coldness	1	0
Infusion site discolouration	1	0
Infusion site joint effusion	1	0
Infusion site joint pain	2	0
Infusion site mass	1	0
Infusion site nerve damage	1	0
Infusion site pain	5	0
Infusion site pruritus	3	0
Infusion site swelling	2	0
Infusion site urticaria	1	0
Infusion site warmth	2	0
Injection site reactions		
Injected limb mobility decreased	38	0
Injection site bruising	73	0
Injection site coldness	1	0
Injection site cyst	3	0
Injection site discolouration	5	0
Injection site discomfort	10	0
Injection site eczema	1	0
Injection site erythema	445	0
Injection site extravasation	1	0
Injection site haematoma	2	0
Injection site haemorrhage	10	0
Injection site hypersensitivity	3	0
Injection site hypoaesthesia	17	0
Injection site indentation	10	0
Injection site induration	4	0
Injection site inflammation	50	0
Injection site injury	2	0
Injection site irritation	3	0
Injection site joint discomfort	2	0
Injection site joint erythema	4	0
Injection site joint movement impairment	1	0
Injection site joint pain	15	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	645	0
Injection site movement impairment	1	0
Injection site muscle weakness	1	0
Injection site necrosis	4	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site nerve damage	1	0
Injection site nodule	1	0
Injection site oedema	19	0
Injection site pain	3223	0
Injection site pallor	1	0
Injection site paraesthesia	15	0
Injection site pruritus	249	0
Injection site rash	205	0
Injection site reaction	58	0
Injection site scab	4	0
Injection site scar	4	0
Injection site swelling	352	0
Injection site urticaria	36	0
Injection site vesicles	10	0
Injection site warmth	211	0
Interactions		
Alcohol interaction	5	0
Drug interaction	32	0
Drug-device interaction	3	0
Inhibitory drug interaction	3	0
Mass conditions NEC		
Cyst	59	0
Mass	91	0
Nodule	45	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	10	0
Mucosal inflammation	3	0
Mucosal ulceration	1	0
Oedema mucosal	2	0
Polyp	5	0
Necrosis NEC		
Fat necrosis	4	0
Necrosis	5	0
Oedema NEC		
Face oedema	37	0
Generalised oedema	6	0
Localised oedema	21	0
Oedema	95	0
Oedema peripheral	104	0
Pain and discomfort NEC		
Axillary pain	4075	0
Breakthrough pain	1	0
Chest discomfort	2097	0
Chest pain	6905	0
Discomfort	590	0
Facial discomfort	21	0
Facial pain	241	0
First bite syndrome	1	0
Inflammatory pain	21	0
Non-cardiac chest pain	36	0
Pain	10173	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Suprapubic pain	1	0
Tenderness	745	0
Visceral pain	2	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	45	0
Adverse food reaction	3	0
Adverse reaction	2	0
Drug ineffective	559	0
Drug intolerance	4	0
Drug resistance	1	0
Immediate post-injection reaction	5	0
Inadequate analgesia	9	0
No reaction on previous exposure to drug	26	0
Product intolerance	1	0
Therapeutic product effect decreased	2	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	3	0
Therapeutic response decreased	2	0
Therapeutic response unexpected	99	0
Therapy non-responder	1	0
Treatment failure	12	0
Vaccination failure	117	0
Trophic disorders		
Abnormal organ growth	1	0
Atrophy	3	0
Calcinosis	2	0
Hyperplasia	1	0
Hypertrophy	1	0
Ulcers NEC		
Ulcer	39	0
Ulcer haemorrhage	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	25	0
Shoulder injury related to vaccine administration	71	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	144	0
Vaccination site coldness	4	0
Vaccination site cyst	7	0
Vaccination site dermatitis	2	0
Vaccination site discharge	1	0
Vaccination site discolouration	17	0
Vaccination site discomfort	54	0
Vaccination site dryness	2	0
Vaccination site eczema	1	0
Vaccination site erythema	685	0
Vaccination site granuloma	5	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	34	0
Vaccination site hypersensitivity	5	0
Vaccination site hypoaesthesia	20	0
Vaccination site induration	82	0
Vaccination site inflammation	66	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site injury	1	0
Vaccination site irritation	16	0
Vaccination site joint discomfort	3	0
Vaccination site joint erythema	12	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	22	0
Vaccination site joint pain	35	0
Vaccination site joint swelling	4	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	8	0
Vaccination site macule	1	0
Vaccination site mass	340	0
Vaccination site movement impairment	97	0
Vaccination site necrosis	1	0
Vaccination site nerve damage	1	0
Vaccination site nodule	6	0
Vaccination site oedema	3	0
Vaccination site pain	2422	0
Vaccination site papule	2	0
Vaccination site paraesthesia	10	0
Vaccination site phlebitis	1	0
Vaccination site photosensitivity reaction	1	0
Vaccination site pruritus	190	0
Vaccination site rash	155	0
Vaccination site reaction	37	0
Vaccination site scab	3	0
Vaccination site scar	3	0
Vaccination site swelling	659	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	3	0
Vaccination site urticaria	11	0
Vaccination site vesicles	13	0
Vaccination site warmth	305	0
Vascular complications associated with device		
Vascular stent thrombosis	1	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	48	0
General disorders SOC TOTAL	**122547**	**246**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Hepatic disorders		
Bile duct infections and inflammations		
Biliary colic	19	0
Cholangitis	1	0
Cholecystitis and cholelithiasis		
Cholecystitis	4	0
Cholecystitis acute	2	0
Cholelithiasis	13	0
Cholestasis and jaundice		
Cholestasis	2	0
Cholestasis of pregnancy	1	0
Jaundice	29	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
Gallbladder disorders NEC		
Gallbladder disorder	4	0
Gallbladder enlargement	1	0
Hepatic and hepatobiliary disorders NEC		
Hepatic cyst	1	0
Hepatic lesion	1	0
Liver disorder	17	0
Hepatic enzymes and function abnormalities		
Hepatic function abnormal	9	0
Hypertransaminasaemia	5	0
Hepatic failure and associated disorders		
Acute hepatic failure	2	0
Hepatic failure	2	1
Hepatic fibrosis and cirrhosis		
Hepatic cirrhosis	4	0
Hepatic vascular disorders		
Congestive hepatopathy	2	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	2	0
Hepatic vein thrombosis	5	0
Portal vein thrombosis	8	0
Portosplenomesenteric venous thrombosis	1	0
Hepatobiliary signs and symptoms		
Hepatic pain	37	0
Hepatomegaly	7	0
Liver tenderness	3	0
Hepatocellular damage and hepatitis NEC		
Autoimmune hepatitis	16	0
Drug-induced liver injury	3	0
Hepatic steatosis	5	0
Hepatitis	19	0
Hepatitis acute	4	0
Hepatitis toxic	1	0
Hepatotoxicity	1	0
Immune-mediated hepatic disorder	1	0
Liver injury	28	0
Obstructive bile duct disorders (excl neoplasms)		
Bile duct stenosis	1	0
Hepatic disorders SOC TOTAL	274	1

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Immune system disorders		
Acute and chronic sarcoidosis		
Loefgren syndrome	1	0
Sarcoidosis	20	0
Allergic conditions NEC		
Allergic oedema	19	0
Allergy to animal	2	0
Allergy to arthropod bite	7	0
Allergy to arthropod sting	2	0
Allergy to metals	3	0
Allergy to sting	1	0
Hypersensitivity	1177	0
Infusion related hypersensitivity reaction	3	0
Mite allergy	2	0
Multiple allergies	17	0
Serum sickness	3	0
Serum sickness-like reaction	6	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	4	0
Type IV hypersensitivity reaction	7	0
Allergies to foods, food additives, drugs and other chemicals		
Allergic reaction to excipient	7	0
Allergy to chemicals	7	0
Allergy to vaccine	50	0
Contrast media reaction	2	0
Drug hypersensitivity	43	0
Food allergy	46	0
Milk allergy	3	0
Oral allergy syndrome	3	0
Polymers allergy	1	0
Reaction to colouring	1	0
Reaction to excipient	11	0
Reaction to preservatives	5	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	567	2
Anaphylactic shock	67	0
Anaphylactoid reaction	25	0
Anaphylactoid shock	4	0
Atopic disorders		
Atopy	3	0
Seasonal allergy	116	0
Autoimmune disorders NEC		
Autoimmune disorder	60	0
Autoinflammatory diseases		
Autoinflammatory disease	1	0
Immune and associated conditions NEC		
Anamnestic reaction	1	0
Bacille Calmette-Guerin scar reactivation	67	0
Cytokine release syndrome	1	0
Cytokine storm	1	0
Decreased immune responsiveness	4	0
Graft versus host disease	2	0

Case Series Drug Analysis Print

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Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
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Reaction Name	Total	Fatal
Immune system disorders (Immune system disorders cont'd)		
Haemophagocytic lymphohistiocytosis	4	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	40	0
Immune-mediated adverse reaction	7	0
Immunisation reaction	58	0
Multisystem inflammatory syndrome in children	6	0
Sensitisation	9	0
Systemic immune activation	2	0
Immunodeficiency disorders NEC		
Hypogammaglobulinaemia	1	0
Immunodeficiency	7	0
Immunosuppression	4	0
Transplant rejections		
Corneal graft rejection	10	0
Kidney transplant rejection	2	0
Solid organ transplant rejection	1	0
Transplant rejection	2	0
Immune system disorders SOC TOTAL	**2529**	**2**

Case Series Drug Analysis Print

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Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections		
Abdominal and gastrointestinal infections		
Abdominal abscess	3	0
Abdominal infection	2	0
Anal abscess	3	0
Anorectal infection	1	0
Appendicitis	50	0
Appendicitis perforated	7	0
Complicated appendicitis	1	0
Diarrhoea infectious	1	0
Diverticulitis	19	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	34	0
Gastrointestinal infection	1	0
Mesenteric abscess	1	0
Peritonitis	3	1
Rectal abscess	1	0
Adenoviral infections		
Adenoviral conjunctivitis	1	0
Adenovirus infection	1	0
Aspergillus infections		
Bronchopulmonary aspergillosis	1	0
Bacterial infections NEC		
Abscess bacterial	2	0
Administration site cellulitis	2	0
Arthritis bacterial	4	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	17	0
Bacterial sepsis	1	0
Bacterial vaginosis	2	0
Cellulitis	205	0
Cellulitis orbital	2	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
External ear cellulitis	1	0
Folliculitis	20	0
Gangrene	2	0
Gastrointestinal bacterial overgrowth	1	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Myocarditis bacterial	1	0
Paronychia	3	0
Perichondritis	3	0
Periorbital cellulitis	3	0
Pneumonia bacterial	5	0
Sinusitis bacterial	2	0
Skin bacterial infection	4	0
Small intestine gangrene	1	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	21	0
Zoonotic bacterial infection	1	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Bartonella infections		
Cat scratch disease	1	0
Bone and joint infections		
Abscess jaw	1	0
Arthritis infective	3	0
Intervertebral discitis	1	0
Osteomyelitis	3	0
Osteomyelitis acute	2	0
Osteomyelitis chronic	1	0
Bordetella infections		
Pertussis	1	0
Borrelial infections		
Lyme disease	4	0
Relapsing fever	1	0
Breast infections		
Breast abscess	3	0
Mastitis	87	0
Caliciviral infections		
Gastroenteritis norovirus	3	0
Campylobacter infections		
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
Candida infections		
Anal candidiasis	3	0
Balanitis candida	1	0
Candida infection	75	0
Oral candidiasis	43	0
Respiratory moniliasis	1	0
Skin candida	2	0
Systemic candida	1	0
Urinary tract candidiasis	1	0
Vulvovaginal candidiasis	56	0
Cardiac infections		
Cardiac infection	1	0
Cardiac valve vegetation	1	0
Endocarditis	2	0
Myocarditis infectious	1	0
Myocarditis septic	1	0
Pericarditis infective	4	0
Central nervous system and spinal infections		
Brain abscess	2	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	23	0
Encephalomyelitis	1	0
Meningitis	11	0
Meningitis aseptic	3	0
Myelitis	14	0
Subdural abscess	1	0
Clostridia infections		
Clostridium difficile infection	2	0
Coronavirus infections		
Asymptomatic COVID-19	21	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections Infections cont'd		
COVID-19	2895	42
COVID-19 pneumonia	53	15
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	13	0
Severe acute respiratory syndrome	4	0
Suspected COVID-19	101	4
Corynebacteria infections		
Diphtheria	2	0
Coxiella infections		
Q fever	13	0
Cytomegaloviral infections		
Cytomegalovirus colitis	1	0
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
Dental and oral soft tissue infections		
Abscess oral	6	0
Gingival abscess	1	0
Gingivitis	15	0
Oral infection	1	0
Parotitis	15	0
Pericoronitis	3	0
Periodontitis	1	0
Pulpitis dental	2	0
Sialoadenitis	3	0
Tongue abscess	1	0
Tooth abscess	8	0
Tooth infection	10	0
Ear infections		
Ear infection	104	0
Labyrinthitis	116	0
Mastoiditis	3	0
Otitis externa	7	0
Otitis media	4	0
Otitis media acute	1	0
Otitis media chronic	5	0
Ectoparasitic infestations		
Acarodermatitis	6	0
Bed bug infestation	1	0
Demodicidosis	1	0
Lice infestation	1	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	5	0
Epstein-Barr virus infection reactivation	2	0
Infectious mononucleosis	31	0
Escherichia infections		
Escherichia bacteraemia	1	0
Escherichia infection	1	0
Eye and eyelid infections		
Conjunctivitis	88	0
Eye abscess	1	0
Eye infection	30	0
Eye infection intraocular	1	0
Eyelid boil	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Eyelid infection	2	0
Hordeolum	30	0
Keratouveitis	1	0
Orbital infection	1	0
Periorbital infection	2	0
Female reproductive tract infections		
Bartholin's abscess	1	0
Bartholinitis	1	0
Endometritis	3	0
Fallopian tube abscess	1	0
Funisitis	1	0
Ovarian abscess	1	0
Pelvic inflammatory disease	2	0
Vaginal infection	3	0
Vulval abscess	1	0
Vulvitis	1	0
Fungal infections NEC		
Fungal infection	20	0
Fungal skin infection	5	0
Mycotoxicosis	1	0
Myocarditis mycotic	2	0
Onychomycosis	3	0
Oral fungal infection	2	0
Pneumonia fungal	2	0
Severe asthma with fungal sensitisation	2	0
Vulvovaginal mycotic infection	8	0
Helminthic infections NEC		
Helminthic infection	1	0
Hepatitis virus infections		
Hepatitis A	2	0
Hepatitis E	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	3	0
Cholecystitis infective	2	0
Hepatic infection	1	0
Herpes viral infections		
Eczema herpeticum	4	0
Genital herpes	97	0
Genital herpes simplex	6	0
Genital herpes zoster	1	0
Herpes ophthalmic	3	0
Herpes simplex	35	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	3	0
Herpes virus infection	13	0
Herpes zoster	1655	0
Herpes zoster disseminated	1	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	17	0
Herpes zoster reactivation	5	0
Meningitis herpes	1	0
Nasal herpes	5	0
Ophthalmic herpes simplex	3	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Ophthalmic herpes zoster	5	0
Oral herpes	344	0
Varicella	37	0
Varicella zoster virus infection	6	0
Infections NEC		
Abscess	40	0
Abscess limb	9	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Genital abscess	2	0
Groin abscess	2	0
Groin infection	1	0
Infected bite	3	0
Infected cyst	2	0
Infection	290	0
Infection susceptibility increased	2	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	41	0
Lymph gland infection	19	0
Lymph node abscess	7	0
Opportunistic infection	1	0
Pathogen resistance	1	0
Purulent discharge	1	0
Respiratory tract infection	15	0
Superinfection	1	0
Vaccination site abscess	12	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	2	0
Infectious transmissions		
Nosocomial infection	1	0
Secondary transmission	8	0
Vaccine virus shedding	1	0
Influenza viral infections		
H1N1 influenza	1	0
Influenza	1814	0
Klebsiella infections		
Klebsiella infection	1	0
Lower respiratory tract and lung infections		
Bronchitis	30	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	311	10
Pneumonia	185	17
Pneumonia aspiration	11	7
Sputum purulent	1	0
Male reproductive tract infections		
Epididymitis	10	0
Orchitis	6	0
Prostate infection	2	0
Molluscum contagiosum viral infections		
Molluscum contagiosum	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Mumps viral infections		
Mumps	9	0
Muscle and soft tissue infections		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	2	0
Psoas abscess	1	0
Soft tissue infection	2	0
Neisseria infections		
Gonorrhoea	1	0
Meningococcal bacteraemia	1	0
Meningococcal infection	1	0
Orthopox viral infections		
Smallpox	1	0
Vaccinia virus infection	2	0
Plasmodia infections		
Malaria	2	0
Pneumocystis infections		
Pneumocystis jirovecii pneumonia	2	0
Pseudomonal infections		
Pseudomonas infection	1	0
Retroviral infections		
Acquired immunodeficiency syndrome	1	0
HIV infection	2	0
Persistent generalised lymphadenopathy	1	0
Rhinoviral infections		
Rhinovirus infection	1	0
Rotaviral infections		
Gastroenteritis rotavirus	1	0
Rubeola viral infections		
Measles	5	0
Salmonella infections		
Typhoid fever	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Neutropenic sepsis	4	1
Sepsis	74	11
Sepsis syndrome	2	0
Septic rash	3	0
Septic shock	6	1
Urosepsis	6	0
Skin structures and soft tissue infections		
Abscess sweat gland	1	0
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	3	0
Eczema infected	1	0
Impetigo	11	0
Infected skin ulcer	4	0
Injection site pustule	3	0
Nail infection	2	0
Pustule	21	0
Pyoderma	1	0
Rash pustular	12	0

Case Series Drug Analysis Print

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Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Skin infection	34	0
Subcutaneous abscess	12	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
Staphylococcal infections		
Furuncle	46	1
Pneumonia staphylococcal	1	0
Septic arthritis staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	5	0
Staphylococcal sepsis	1	0
Streptococcal infections		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	8	0
Pneumonia pneumococcal	1	0
Scarlet fever	1	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	2	0
Streptococcal sepsis	1	0
Tinea infections		
Body tinea	6	0
Tinea capitis	1	0
Tinea infection	1	0
Tinea pedis	3	0
Tinea versicolour	4	0
Toxoplasma infections		
Toxoplasmosis	1	0
Treponema infections		
Syphilis	2	0
Trypanosomal infections		
African trypanosomiasis	4	0
Tuberculous infections		
Disseminated Bacillus Calmette-Guerin infection	1	0
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0
Tuberculosis of central nervous system	1	0
Upper respiratory tract infections		
Acute sinusitis	5	0
Chronic sinusitis	6	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	35	0
Nasopharyngitis	1191	1
Peritonsillar abscess	6	0
Pharyngitis	39	0
Rhinitis	58	0
Sinusitis	209	0
Tonsillitis	146	0
Tracheitis	5	0
Tracheostomy infection	1	0
Upper respiratory tract infection	12	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Urinary tract infections		
Cystitis	86	0
Kidney infection	56	0
Pyelonephritis	3	0
Urethritis	2	0
Urinary tract infection	223	0
Vascular infections		
Haematoma infection	1	0
Infected lymphocele	2	0
Infusion site infection	1	0
Lymphangitis	14	0
Viral infections NEC		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Ear infection viral	1	0
Encephalitis viral	6	1
Eye infection viral	2	0
Gastroenteritis viral	34	0
Hepatitis viral	4	0
Meningitis viral	9	0
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	2	0
Pneumonia viral	5	2
Post viral fatigue syndrome	63	0
Sweating fever	128	0
Vestibular neuronitis	35	0
Viral diarrhoea	2	0
Viral infection	68	0
Viral labyrinthitis	4	0
Viral myocarditis	5	0
Viral pericarditis	3	0
Viral pharyngitis	24	0
Viral rash	69	0
Viral sinusitis	1	0
Viral tonsillitis	2	0
Infections SOC TOTAL	12553	116

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Injuries		
Abdominal and gastrointestinal injuries NEC		
Gallbladder injury	1	0
Gingival injury	1	0
Liver contusion	1	0
Mouth injury	3	0
Oral contusion	5	0
Oral mucosal scar	1	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	7	0
Tongue injury	2	0
Tooth fracture	1	0
Tooth injury	1	0
Accidental exposures to product		
Accidental exposure to product	21	0
Anaesthetic and allied procedural complications		
Airway complication of anaesthesia	2	0
Delayed recovery from anaesthesia	3	0
Atmospheric pressure injuries		
Barotitis media	1	0
Barotrauma	2	0
Hypobarism	2	0
Bone and joint injuries NEC		
Bursa injury	3	0
Joint injury	12	0
Meniscus injury	2	0
Cardiac and vascular procedural complications		
Ischaemic contracture of the left ventricle	1	0
Shunt blood flow excessive	1	0
Vascular pseudoaneurysm	1	0
Cardiovascular injuries		
Vascular injury	9	0
Cerebral injuries NEC		
Brain contusion	4	0
Brain herniation	2	0
Concussion	5	0
Craniocerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	6	0
Subdural haemorrhage	7	0
Traumatic intracranial haemorrhage	1	1
Chemical injuries		
Chemical burn	1	0
Chemical burn of skin	9	0
Chemical cystitis	2	0
Chest and respiratory tract injuries NEC		
Bronchial injury	1	0
Chest crushing	15	0
Foreign body in throat	2	0
Traumatic lung injury	1	0
Conditions caused by cold		
Chillblains	75	0
Cold shock response	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Frostbite	1	0
Cranial nerve injuries		
IIIrd nerve injury	1	0
Vth nerve injury	1	0
Ear injuries NEC		
Deafness traumatic	1	0
Ear injury	2	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	10	0
Exposure via breast milk	155	0
Foetal exposure during pregnancy	72	0
Foetal exposure timing unspecified	1	0
Maternal exposure before pregnancy	31	0
Maternal exposure during breast feeding	2022	0
Maternal exposure during pregnancy	1095	0
Maternal exposure timing unspecified	15	0
Paternal exposure before pregnancy	3	0
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	3	0
Exposure to vaccinated person	4	0
Eye and ear procedural complications		
Toxic anterior segment syndrome	1	0
Eye injuries NEC		
Corneal abrasion	1	0
Eye contusion	18	0
Eye injury	33	0
Foreign body in eye	4	0
Injury corneal	1	0
Periorbital haematoma	1	0
Retinal injury	2	0
Superficial injury of eye	1	0
Foetal and neonatal conditions associated with product exposure		
Intoxication by breast feeding	1	0
Fractures and dislocations NEC		
Fracture	3	0
Joint dislocation	4	0
Multiple fractures	1	0
Gastrointestinal and hepatobiliary procedural complications		
Diversion colitis	1	0
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	11	0
Procedural vomiting	2	0
Heat injuries (excl thermal burns)		
Heat cramps	2	0
Heat exhaustion	3	0
Heat illness	2	0
Heat oedema	14	0
Heat stroke	3	0
Intentional product use issues		
Intentional dose omission	1	0
Intentional product use issue	1	0
Limb fractures and dislocations		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Ankle fracture	1	0
Atypical femur fracture	1	0
Clavicle fracture	27	0
Femoral neck fracture	1	0
Femur fracture	1	0
Fibula fracture	1	0
Hip fracture	2	0
Lower limb fracture	1	0
Tibia fracture	1	0
Upper limb fracture	1	0
Wrist fracture	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	2	0
Dose calculation error	1	0
Inadequate aseptic technique in use of product	1	0
Medication error	81	0
Prescription drug used without a prescription	3	0
Product use complaint	2	0
Product use issue	34	0
Vaccination error	6	0
Wrong dose	4	0
Wrong drug	11	0
Wrong schedule	1	0
Wrong technique in product usage process	10	0
Muscle, tendon and ligament injuries		
Epicondylitis	25	0
Ligament injury	2	0
Ligament sprain	11	0
Mallet finger	1	0
Muscle hernia	1	0
Muscle injury	43	0
Muscle rupture	10	0
Muscle strain	38	0
Post-traumatic neck syndrome	3	0
Tendon injury	7	0
Tendon rupture	26	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	121	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	1	0
Post procedural stroke	1	0
Procedural dizziness	13	0
Non-occupational environmental exposures		
Exposure to extreme temperature	2	0
Non-site specific injuries NEC		
Accident	2	0
Animal scratch	1	0
Arthropod bite	11	0
Arthropod sting	6	0
Bite	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Bone contusion	2	0
Crush injury	1	0
Electric shock	20	0
Fall	221	0
Foreign body	6	0
Injury	14	0
Multiple injuries	2	0
Nervous system injury	2	0
Post concussion syndrome	2	0
Traumatic haematoma	1	0
Wound	7	0
Wound complication	12	0
Wound haematoma	1	0
Wound haemorrhage	3	0
Wound secretion	7	0
Non-site specific procedural complications		
Administration related reaction	1	0
Anastomotic leak	1	0
Incision site pain	3	0
Infusion related reaction	8	0
Injection related reaction	68	0
Post procedural complication	5	0
Post procedural erythema	1	0
Post procedural inflammation	1	0
Post procedural pruritus	1	0
Procedural pain	4	0
Seroma	1	0
Occupational exposures		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
Off label uses		
Off label use	502	0
Overdoses NEC		
Intentional overdose	1	0
Overdose	56	0
Pathways and sources of exposure		
Exposure via contaminated device	1	0
Exposure via unknown route	1	0
Pelvic fractures and dislocations		
Pelvic fracture	1	0
Peripheral nerve injuries		
Axillary nerve injury	1	0
Brachial plexus injury	1	0
Radial nerve injury	2	0
Sciatic nerve injury	2	0
Ulnar nerve injury	6	0
Poisoning and toxicity		
Alcohol poisoning	1	0
Poisoning	14	0
Toxicity to various agents	5	0
Product administration errors and issues		
Accidental overdose	8	0
Contraindicated product administered	3	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Duplicate therapy error	1	0
Expired product administered	14	0
Inappropriate schedule of product administration	743	0
Incomplete course of vaccination	2	0
Incorrect dose administered	64	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	12	0
Lack of vaccination site rotation	1	0
Poor quality product administered	5	0
Product administered at inappropriate site	25	0
Product administered to patient of inappropriate age	3	0
Product administration error	22	0
Product dose omission issue	6	0
Wrong product administered	20	0
Product confusion errors and issues		
Product dosage form confusion	1	0
Product label confusion	6	0
Product packaging confusion	2	0
Product dispensing errors and issues		
Product dispensing error	4	0
Product monitoring errors and issues		
Drug monitoring procedure incorrectly performed	1	0
Product preparation errors and issues		
Product preparation error	3	0
Product preparation issue	6	0
Product prescribing errors and issues		
Contraindicated product prescribed	2	0
Product prescribing error	2	0
Product selection errors and issues		
Product selection error	2	0
Radiation injuries		
Sunburn	24	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Foreign body in urogenital tract	1	0
Reproductive system and breast injuries		
Breast injury	1	0
Cervix injury	1	0
Penile contusion	1	0
Penis injury	2	0
Uterine rupture	1	0
Reproductive tract and breast procedural complications		
Failed in vitro fertilisation	1	0
Site specific injuries NEC		
Back injury	4	0
Face crushing	3	0
Face injury	1	0
Head injury	36	0
Limb crushing injury	4	0
Limb injury	208	0
Nasal injury	2	0
Neck crushing	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Neck injury	1	0
Pharyngeal contusion	1	0
Site specific procedural complications NEC		
Axillary web syndrome	3	0
Skin injuries NEC		
Contusion	1399	0
Hair injury	2	0
Nail avulsion	1	0
Scar	37	0
Scratch	9	0
Skin abrasion	7	0
Skin injury	5	0
Skin laceration	4	0
Skin wound	3	0
Splinter	1	0
Subcutaneous haematoma	2	0
Skin procedural complications		
Dermal filler overcorrection	1	0
Recall phenomenon	1	0
Skin procedural complication	1	0
Skull fractures, facial bone fractures and dislocations		
Facial bones fracture	1	0
Fractured skull depressed	1	0
Spinal cord injuries NEC		
Spinal cord injury cervical	1	0
Spinal fractures and dislocations		
Spinal compression fracture	1	0
Spinal fracture	4	0
Stoma complications		
Gastrointestinal stoma complication	2	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
Thermal burns		
Airway burns	1	0
Burn oesophageal	4	0
Burn of internal organs	4	0
Burn oral cavity	6	0
Burns second degree	3	0
Burns third degree	1	0
Cold burn	1	0
Thermal burn	28	0
Thermal burns of eye	17	0
Underdoses NEC		
Underdose	6	0
Vaccination related complications		
Adverse event following immunisation	1	0
Post vaccination syndrome	1	0
Injuries SOC TOTAL	**8079**	**1**

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations		
Adrenal cortex tests		
Cortisol decreased	5	0
Adrenal medulla tests		
Epinephrine	1	0
Epinephrine abnormal	1	0
Epinephrine increased	1	0
Auditory and vestibular diagnostic procedures		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
Weber tuning fork test abnormal	1	0
Autoimmunity analyses		
Antineutrophil cytoplasmic antibody positive	1	0
Antinuclear antibody	3	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	1	0
Beta-2 glycoprotein antibody positive	1	0
Cardiolipin antibody positive	1	0
Rheumatoid factor	3	0
Rheumatoid factor increased	3	0
Rheumatoid factor positive	1	0
Bacteria identification and serology (excl mycobacteria)		
Bacterial test positive	1	0
Blood counts NEC		
Full blood count	7	0
Full blood count abnormal	3	0
Blood gas and acid base analyses		
Acid base balance abnormal	1	0
Blood lactic acid	4	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	5	0
Blood pH	7	0
Blood pH abnormal	1	0
Blood pH increased	12	0
Oxygen consumption	1	0
Oxygen consumption decreased	2	0
Oxygen saturation	12	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	104	0
PCO2 increased	1	0
PO2 decreased	1	0
Venous oxygen saturation decreased	1	0
Blood grouping and cross-matching analyses		
Rhesus antigen positive	1	0
Bone marrow and immune tissue histopathology procedures		
Aspiration bone marrow	1	0
Biopsy lymph gland	2	0
Bone marrow and immune tissue imaging procedures		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose	12	0
Blood glucose abnormal	15	0
Blood glucose decreased	38	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood glucose fluctuation	17	0
Blood glucose increased	115	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
Cardiac auscultatory investigations		
Cardiac murmur	50	0
Heart sounds	10	0
Heart sounds abnormal	6	0
Cardiac function diagnostic procedures		
Cardiac monitoring	1	0
Cardiac output	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Ejection fraction decreased	3	0
Myocardial strain imaging	2	0
Right atrial volume abnormal	1	0
Stroke volume decreased	1	0
Cardiac imaging procedures		
Catheterisation cardiac	1	0
Magnetic resonance imaging heart	1	0
Scan myocardial perfusion abnormal	1	0
Cell marker analyses		
Carbohydrate antigen 15-3 increased	1	0
Carcinoembryonic antigen increased	1	0
HLA-B*27 positive	1	0
Prostatic specific antigen increased	4	0
Central nervous system imaging procedures		
Computerised tomogram head	10	0
Magnetic resonance imaging head	12	0
Magnetic resonance imaging head abnormal	2	0
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure	1	0
CSF protein increased	1	0
Chemistry analyses NEC		
Histamine abnormal	1	0
Histamine level	1	0
Histamine level increased	2	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	5	0
Inflammatory marker test	1	0
Renin	1	0
Cholesterol analyses		
Blood cholesterol increased	13	0
Remnant-like lipoprotein particles	4	0
Coagulation and bleeding analyses		
ADAMTS13 activity decreased	1	0
Activated partial thromboplastin time prolonged	15	0
Activated partial thromboplastin time shortened	1	0
Bleeding time	1	0
Bleeding time abnormal	2	0
Bleeding time prolonged	11	0
Blood thromboplastin	1	0
Clot retraction	1	1

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0
Fibrin D dimer increased	26	0
International normalised ratio abnormal	9	0
International normalised ratio decreased	22	0
International normalised ratio fluctuation	3	0
International normalised ratio increased	53	0
Platelet factor 4	1	0
Prothrombin time prolonged	1	0
Prothrombin time shortened	1	0
Digestive enzymes		
Amylase increased	1	0
ECG investigations		
Electrocardiogram	5	0
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	11	0
Electrocardiogram ST segment depression	2	0
Electrocardiogram ST segment elevation	12	0
Electrocardiogram ST-T segment abnormal	2	0
Electrocardiogram T wave inversion	6	0
Electrocardiogram abnormal	25	0
Electrocardiogram change	1	0
Electrocardiogram normal	3	0
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	86	0
Faecal analyses NEC		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
Fertility analyses		
Infertility tests	1	0
Semen analysis abnormal	1	0
Semen volume increased	1	0
Sperm concentration	2	0
Sperm concentration decreased	2	0
Spermatozoa abnormal	1	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate abnormal	5	2
Foetal heart rate increased	1	0
Foetal monitoring	1	0
Foetal non-stress test	1	0
Gastrointestinal and abdominal imaging procedures		
Computerised tomogram abdomen	1	0
Sigmoidoscopy abnormal	1	0
X-ray with contrast upper gastrointestinal tract	1	0
Gastrointestinal function diagnostic procedures		
Gastric pH decreased	4	0
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood insulin	2	0
Blood insulin decreased	1	0
Gene analyses		

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
EGFR status assay	1	0
Haematological analyses NEC		
Blood viscosity abnormal	1	0
Blood viscosity decreased	1	0
Blood viscosity increased	2	0
Plasma viscosity	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate increased	8	0
Heart rate and pulse investigations		
Carotid pulse	2	0
Carotid pulse abnormal	1	0
Heart rate	600	0
Heart rate abnormal	82	0
Heart rate decreased	109	0
Heart rate increased	1215	0
Heart rate irregular	304	0
Heart rate normal	1	0
Heart rate variability decreased	1	0
Heart rate variability increased	1	0
Maximum heart rate	5	0
Maximum heart rate increased	2	0
Pulse abnormal	24	0
Pulse absent	1	0
Pulse pressure increased	3	0
Radial pulse abnormal	1	0
Sinus rhythm	8	0
Hepatobiliary function diagnostic procedures		
Alanine aminotransferase increased	29	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase abnormal	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	7	0
Gamma-glutamyltransferase	2	0
Gamma-glutamyltransferase increased	5	0
Hepatic enzyme	1	0
Hepatic enzyme increased	10	0
Liver function test	1	0
Liver function test abnormal	36	0
Liver function test increased	30	0
Hepatobiliary imaging procedures		
Computerised tomogram liver	1	0
Liver scan	1	0
Imaging procedures NEC		
Computerised tomogram	4	0
Magnetic resonance imaging	6	0
Magnetic resonance imaging abnormal	1	0
Scan	2	0
X-ray	2	0
Immune response protein analyses NEC		
Cytokine test	1	0
Immunoglobulin analyses		
Blood immunoglobulin E increased	2	0
Blood immunoglobulin G increased	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	2	0
Immunology analyses NEC		
Antibody test	4	0
Antibody test positive	1	0
Immunology test	14	0
Immunology skin tests NEC		
Allergy alert test	2	0
Allergy alert test positive	1	0
Skin test positive	2	0
Investigations NEC		
Blood test	27	0
Blood test abnormal	49	0
Blood test normal	1	0
False positive investigation result	1	0
Laboratory test	1	0
Polymerase chain reaction	1	0
Polymerase chain reaction positive	33	0
Quality of life decreased	1	0
Systemic lupus erythematosus disease activity index increased	1	0
Metabolism tests NEC		
Blood ketone body	3	0
Blood ketone body increased	1	0
Blood ketone body present	1	0
Blood uric acid increased	3	0
Brain natriuretic peptide increased	1	0
N-terminal prohormone brain natriuretic peptide increased	1	0
Ubiquinone	1	0
Urine ketone body	1	0
Urine ketone body present	1	0
Microbiology and serology tests NEC		
Culture negative	1	0
Culture urine	1	0
Nasopharyngeal swab	1	0
Vaccine induced antibody absent	1	0
Mineral and electrolyte analyses		
Blood calcium increased	1	0
Blood copper increased	1	0
Blood iron	4	0
Blood iron decreased	14	0
Blood iron increased	1	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	5	0
Blood potassium increased	3	0
Blood sodium decreased	11	0
Serum ferritin	2	0
Serum ferritin abnormal	1	0
Serum ferritin decreased	5	0
Serum ferritin increased	3	0
Sweat test	2	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Urine copper	2	0
Musculoskeletal and soft tissue histopathology procedures		
Biopsy bone	1	0
Musculoskeletal and soft tissue imaging procedures		
Skull X-ray	6	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count	1	0
Swollen joint count increased	1	0
Mycobacteria identification and serology		
Tuberculin test positive	1	0
Neurologic diagnostic procedures		
Balance test	1	0
Coma scale abnormal	5	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	6	0
Magnetic resonance neurography	1	0
Nerve conduction studies	1	0
Pain threshold decreased	1	0
Sensory level	2	0
Temperature perception test abnormal	1	0
Temperature perception test increased	1	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	1	0
Intraocular pressure increased	9	0
Intraocular pressure test	3	0
Pupil dilation procedure	1	0
Visual acuity tests	1	0
Physical examination procedures and organ system status		
Body temperature	299	0
Body temperature abnormal	55	0
Body temperature decreased	48	0
Body temperature fluctuation	69	0
Body temperature increased	537	0
Body temperature normal	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	3	0
Grip strength decreased	27	0
Gynaecological examination	1	0
Head lag	9	0
Intelligence test	1	0
Lymph node palpable	45	0
Male genital examination abnormal	1	0
Menstruation normal	4	0
Muscle strength abnormal	5	0
Ophthalmological examination	3	0
Orthopaedic examination	1	0
Palpatory finding abnormal	2	0
Product residue present	2	0
Psoriasis area severity index decreased	2	0
Psoriasis area severity index increased	1	0
Respiratory rate	9	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Respiratory rate decreased	28	0
Respiratory rate increased	49	0
Skin temperature	48	0
Temperature difference of extremities	13	0
Weight	1	0
Weight abnormal	1	0
Weight decreased	140	0
Weight increased	55	0
Pituitary analyses anterior		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	3	0
Blood growth hormone	3	0
Blood prolactin	3	0
Blood prolactin increased	4	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	11	0
Platelet analyses		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	3	0
Platelet count abnormal	1	0
Platelet count decreased	89	0
Platelet count increased	6	0
Protein analyses NEC		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	32	0
Red blood cell analyses		
Haematocrit	1	0
Haematocrit decreased	1	0
Haematocrit increased	1	0
Haemoglobin decreased	16	0
Haemoglobin increased	2	0
Red blood cell count decreased	1	0
Red blood cell count increased	1	0
Red blood cell rouleaux formation present	1	0
Renal function analyses		
Blood creatine decreased	1	0
Blood creatinine	2	0
Blood creatinine decreased	1	0
Blood creatinine increased	5	0
Glomerular filtration rate decreased	4	0
Glomerular filtration rate increased	1	0
Reproductive hormone analyses		
Blood oestrogen	2	0
Blood oestrogen decreased	2	0
Blood testosterone decreased	2	0
Blood testosterone increased	2	0
False negative pregnancy test	9	0
Female sex hormone level	3	0
Human chorionic gonadotropin increased	1	0
Pregnancy test	18	0
Pregnancy test false positive	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Pregnancy test positive	1	0
Progesterone decreased	1	0
Reproductive organ and breast histopathology procedures		
Biopsy breast	2	0
Biopsy endometrium	1	0
Smear cervix	3	0
Reproductive organ and breast imaging procedures		
Breast scan	1	0
Hysteroscopy	2	0
Respiratory and pulmonary function diagnostic procedures		
Airway peak pressure increased	1	0
Forced expiratory volume	1	0
Forced expiratory volume increased	3	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	2	0
Peak expiratory flow rate	2	0
Peak expiratory flow rate decreased	7	0
Pulmonary function test	3	0
Spirometry abnormal	1	0
Total lung capacity decreased	4	0
Vital capacity	1	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	3	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray	19	0
Chest X-ray abnormal	1	0
Chest X-ray normal	2	0
Chest scan	2	0
Computerised tomogram thorax	2	0
Ventilation/perfusion scan	2	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	12	0
Muscle enzyme	1	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	3	0
Troponin I increased	2	0
Troponin T increased	2	0
Troponin increased	29	0
Therapeutic drug monitoring analyses		
Analgesic drug level	9	0
Anticoagulation drug level above therapeutic	1	0
Anticoagulation drug level below therapeutic	5	0
Anticoagulation drug level increased	1	0
Drug level decreased	1	0
Thyroid analyses		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	1	0
Thyroxine	1	0
Thyroxine decreased	1	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	5	0
Tissue enzyme analyses NEC		

Case Series Drug Analysis Print

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Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood alkaline phosphatase abnormal	1	0
Blood alkaline phosphatase increased	6	0
Blood lactate dehydrogenase	1	0
Blood lactate dehydrogenase increased	1	0
Enzyme level increased	1	0
Toxicology laboratory analyses		
Blood caffeine decreased	1	0
Blood lead	1	0
Drug screen positive	2	0
Opiates	1	0
Toxicologic test abnormal	1	0
Urinalysis NEC		
Blood urine	19	0
Blood urine present	80	0
Cells in urine	1	0
Glucose urine present	1	0
Protein urine	1	0
Protein urine absent	1	0
Protein urine present	1	0
Red blood cells urine	1	0
Urine analysis abnormal	6	0
Urine leukocyte esterase positive	1	0
Urine uric acid increased	1	0
pH urine	6	0
pH urine increased	2	0
Urinary tract function analyses NEC		
Urine output	14	0
Urine output decreased	15	0
Urine output increased	7	0
Urinary tract histopathology procedures		
Urine cytology	1	0
Urinary tract imaging procedures		
Bladder scan	1	0
Cystoscopy	2	0
Ultrasound kidney normal	1	0
Vascular imaging procedures NEC		
Venogram	2	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	14	0
Blood pressure ambulatory increased	1	0
Blood pressure decreased	92	0
Blood pressure diastolic	2	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	4	0
Blood pressure difference of extremities	1	0
Blood pressure increased	308	0
Blood pressure measurement	49	0
Blood pressure normal	2	0
Blood pressure orthostatic	1	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	4	0
Blood pressure systolic increased	1	0
Virus identification and serology		

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Coronavirus test	11	0
Coronavirus test positive	4	0
Cytomegalovirus test positive	1	0
HIV antibody positive	1	0
HIV test	1	0
SARS-CoV-1 test	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	10	0
SARS-CoV-2 antibody test negative	15	0
SARS-CoV-2 antibody test positive	6	0
SARS-CoV-2 test	36	0
SARS-CoV-2 test false negative	2	0
SARS-CoV-2 test false positive	4	0
SARS-CoV-2 test negative	10	0
SARS-CoV-2 test positive	112	0
Viral load	2	0
Viral test	4	0
Viral test positive	1	0
Vitamin analyses		
Blood folate decreased	8	0
Vitamin B12	1	0
Vitamin B12 abnormal	2	0
Vitamin B12 decreased	3	0
Vitamin D	4	0
Vitamin D decreased	4	0
Water and electrolyte analyses NEC		
Urine osmolarity	1	0
Volume blood	1	0
White blood cell analyses		
Eosinophil count	1	0
Eosinophil count decreased	1	0
Eosinophil count increased	3	0
Lymphocyte count	1	0
Lymphocyte count decreased	3	0
Lymphocyte count increased	1	0
Monocyte count increased	2	0
Neutrophil count	4	0
Neutrophil count decreased	13	0
Neutrophil count increased	4	0
White blood cell count	5	0
White blood cell count decreased	16	0
White blood cell count increased	13	0
Investigations SOC TOTAL	**6506**	**3**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Appetite disorder	23	0
Decreased appetite	1547	0
Diet refusal	1	0
Eating disorder symptom	3	0
Food craving	13	0
Food refusal	16	0
Hyperphagia	15	0
Hypophagia	20	0
Increased appetite	38	0
Salt craving	2	0
Calcium metabolism disorders		
Hypocalcaemia	3	0
Tetany	5	0
Copper metabolism disorders		
Copper deficiency	1	0
Diabetes mellitus (incl subtypes)		
Diabetes mellitus	62	0
Diabetes mellitus inadequate control	18	1
Increased insulin requirement	2	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	16	0
Type 2 diabetes mellitus	5	0
Diabetic complications NEC		
Diabetic complication	2	0
Diabetic ketoacidosis	12	0
Diabetic ketosis	1	0
Disorders of purine metabolism		
Gout	110	0
Electrolyte imbalance NEC		
Electrolyte imbalance	1	0
Fluid imbalance	2	0
Elevated cholesterol		
Hypercholesterolaemia	1	0
Fat soluble vitamin deficiencies and disorders		
Vitamin D deficiency	11	0
Fluid intake decreased		
Fluid intake reduced	2	0
Fluid intake increased		
Polydipsia	7	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Alcohol intolerance	8	0
Breast milk substitute intolerance	1	0
Dairy intolerance	3	0
Food intolerance	23	0
Gluten sensitivity	7	0
Histamine intolerance	7	0
General nutritional disorders NEC		
Abnormal loss of weight	42	0
Abnormal weight gain	21	0
Cachexia	1	0
Feeding disorder	114	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Food aversion	14	0
Malnutrition	3	0
Neonatal insufficient breast milk syndrome	7	0
Obesity	1	0
Overweight	1	0
Poor feeding infant	17	0
Weight loss poor	3	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	2	0
Hyperglycaemia	69	0
Insulin resistance	5	0
Hyperlipidaemias NEC		
Hyperlipidaemia	1	0
Hypoglycaemic conditions NEC		
Glycopenia	1	0
Hypoglycaemia	84	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	3	0
Iron deficiencies		
Iron deficiency	13	0
Iron excess		
Haemochromatosis	2	0
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Body fat disorder	1	0
Magnesium metabolism disorders		
Hypomagnesaemia	1	0
Magnesium deficiency	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	7	1
Lactic acidosis	3	0
Metabolic acidosis	4	0
Metabolic disorders NEC		
Hypercarotinaemia	1	0
Hypercatabolism	1	0
Hypometabolism	1	0
Metabolic disorder	1	0
Mixed acid-base disorders		
Acidosis	4	0
Phosphorus metabolism disorders		
Hypophosphataemia	1	0
Potassium imbalance		
Hyperkalaemia	6	0
Hypokalaemia	5	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hypernatraemia	1	0
Hyponatraemia	12	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	5	0
Total fluid volume decreased		

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022
Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968
MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Dehydration	245	0
Total fluid volume increased		
Fluid retention	67	0
Hypervolaemia	5	0
Vitamin deficiencies NEC		
Hypovitaminosis	6	0
Water soluble vitamin deficiencies		
Folate deficiency	11	0
Vitamin B complex deficiency	1	0
Vitamin B12 deficiency	8	0
Metabolic disorders SOC TOTAL	**2800**	**2**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	412	0
Arthropathy	35	0
Autoimmune arthritis	10	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	3	0
Polyarthritis	17	0
Rheumatic fever	2	0
Sacroiliitis	6	0
Seronegative arthritis	4	0
Bone disorders NEC		
Bone cyst	2	0
Exostosis	1	0
Jaw disorder	4	0
Medial tibial stress syndrome	6	0
Osteitis	9	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	2	0
Bone related signs and symptoms		
Bone pain	460	0
Bone swelling	10	0
Coccydynia	4	0
Metatarsalgia	1	0
Pain in jaw	436	0
Pubic pain	2	0
Spinal pain	102	0
Bursal disorders		
Bursitis	105	0
Cartilage disorders		
Chondritis	1	0
Costochondritis	145	0
Osteochondritis	1	0
Polychondritis	3	0
Connective tissue disorders NEC		
Connective tissue disorder	3	0
Polymyalgia rheumatica	92	0
Reynold's syndrome	3	0
Scleroderma	1	0
Sjogren's syndrome	9	0
Systemic scleroderma	1	0
Crystal arthropathic disorders		
Chondrocalcinosis pyrophosphate	3	0
Crystal arthropathy	2	0
Gouty arthritis	2	0
Epiphyseal disorders		
Epiphyses premature fusion	1	0
Extremity deformities		
Bone deformity	1	0
Finger deformity	3	0
Foot deformity	4	0
Hand deformity	4	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Knee deformity	1	0
Limb deformity	6	0
Musculoskeletal deformity	1	0
Fractures NEC		
Osteoporotic fracture	1	0
Intervertebral disc disorders NEC		
Intervertebral disc protrusion	3	0
Joint related disorders NEC		
Carpal collapse	1	0
Chondromalacia	1	0
Greater trochanteric pain syndrome	2	0
Hypermobility syndrome	1	0
Joint ankylosis	1	0
Joint deposit	1	0
Joint destruction	1	0
Joint instability	2	0
Joint laxity	3	0
Joint lock	36	0
Ligament laxity	1	0
Patellofemoral pain syndrome	2	0
Periarthritis	278	0
Rotator cuff syndrome	43	0
Temporomandibular joint syndrome	16	0
Joint related signs and symptoms		
Arthralgia	10632	0
Jaw clicking	7	0
Joint effusion	16	0
Joint noise	44	0
Joint range of motion decreased	39	0
Joint stiffness	309	0
Joint swelling	693	0
Joint vibration	4	0
Joint warmth	17	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	4	0
Ligamentitis	3	0
Symphysiolysis	1	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	30	0
Metabolic bone disorders		
Osteopenia	4	0
Osteoporosis	7	0
Muscle infections and inflammations		
Antisynthetase syndrome	3	0
Immune-mediated myositis	2	0
Myositis	53	0
Polymyositis	9	0
Muscle pains		
Fibromyalgia	145	0
Myalgia	11912	0
Myalgia intercostal	2	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Myofascial pain syndrome	13	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0
Muscle atrophy	33	0
Muscle discomfort	8	0
Muscle disorder	12	0
Muscle fatigue	406	0
Muscle haemorrhage	1	0
Muscle mass	5	0
Muscle oedema	5	0
Muscle spasms	2370	0
Muscle swelling	45	0
Muscle tightness	113	0
Muscle twitching	569	0
Myofascial spasm	1	0
Muscle tone abnormalities		
Muscle rigidity	25	0
Nuchal rigidity	13	0
Torticollis	7	0
Trismus	42	0
Muscle weakness conditions		
Muscular weakness	1199	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	5	0
Chest wall mass	1	0
Growth disorder	2	0
Limb mass	24	0
Mandibular mass	3	0
Mastication disorder	8	0
Mobility decreased	161	0
Muscle contracture	1	0
Musculoskeletal disorder	13	0
Musculoskeletal stiffness	1524	0
Pelvic misalignment	1	0
Posture abnormal	2	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	5	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Facial asymmetry	1	0
Head deformity	2	0
Nose deformity	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Connective tissue inflammation	1	0
Dactylitis	3	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	18	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	2913	0
Flank pain	87	0
Growing pains	1	0
Limb discomfort	1687	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Musculoskeletal chest pain	316	0
Musculoskeletal discomfort	130	0
Musculoskeletal pain	145	0
Neck pain	2261	0
Pain in extremity	14741	1
Rheumatic disorder	17	0
Sacral pain	4	0
Myopathies		
Mitochondrial myopathy acquired	1	0
Myopathy	9	0
Rhabdomyolysis	14	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	67	0
Spinal osteoarthritis	2	0
Psoriatic arthropathies		
Psoriatic arthropathy	28	0
Rheumatoid arthropathies		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	151	0
Rheumatoid nodule	1	0
Still's disease	2	0
Soft tissue disorders NEC		
Axillary mass	322	0
Fistula	1	0
Fistula discharge	1	0
Fluctuance	1	0
Groin pain	128	0
Neck mass	47	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue necrosis	1	0
Soft tissue swelling	7	0
Spine and neck deformities		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spinal stenosis	3	0
Spondyloarthropathies		
Ankylosing spondylitis	10	0
Arthritis reactive	79	0
Spondylitis	4	0
Spondyloarthropathy	1	0
Synovial disorders		
Synovial cyst	23	0
Synovitis	12	0
Tendon disorders		
Enthesopathy	3	0
Posterior tibial tendon dysfunction	1	0
Tendon disorder	7	0
Tendon pain	27	0
Tendonitis	65	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Tenosynovitis	4	0
Tenosynovitis stenosans	2	0
Trigger finger	34	0
Trunk deformities		
Deformity thorax	1	0
Drooping shoulder syndrome	3	0
Shoulder deformity	4	0
Muscle & tissue disorders SOC TOTAL	**56287**	**1**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Neoplasms		
Adrenal neoplasms malignant		
Adrenal gland cancer	1	0
Angioimmunoblastic T-cell lymphomas		
Angioimmunoblastic T-cell lymphoma	1	0
B-cell lymphomas NEC		
B-cell lymphoma	2	1
Follicular lymphoma	4	0
Bile duct neoplasms malignant		
Bile duct cancer	1	0
Bone neoplasms malignant (excl sarcomas)		
Bone cancer	1	1
Bone neoplasms unspecified malignancy		
Bone neoplasm	1	0
Breast and nipple neoplasms benign		
Benign breast neoplasm	3	0
Fibroadenoma of breast	2	0
Breast and nipple neoplasms malignant		
Breast cancer	45	0
Breast cancer female	1	0
Breast cancer male	2	0
Breast cancer stage I	1	0
Breast cancer stage III	3	0
HER2 positive breast cancer	1	0
Inflammatory carcinoma of the breast	1	0
Invasive ductal breast carcinoma	1	0
Triple negative breast cancer	4	0
Cardiovascular neoplasms benign		
Haemangioma	2	0
Pericardial lipoma	1	0
Cardiovascular neoplasms malignant and unspecified		
Cardiac neoplasm unspecified	1	0
Cartilage sarcomas		
Chondrosarcoma	1	0
Central nervous system neoplasms malignant NEC		
Brain cancer metastatic	1	0
Cervix neoplasms malignant		
Cervix carcinoma	3	0
Colorectal neoplasms malignant		
Colon cancer	2	0
Colorectal cancer	2	0
Rectal cancer	2	0
Endocrine neoplasms benign NEC		
Pituitary tumour benign	1	0
Endocrine neoplasms malignant and unspecified NEC		
Neuroendocrine tumour	1	0
Thyroid neoplasm	1	0
Endometrial neoplasms malignant		
Endometrial cancer	2	0
Follicular lymphomas		
Primary gastrointestinal follicular lymphoma	1	0
Gastric neoplasms malignant		
Gastric cancer	1	1
Gastrointestinal neoplasms malignant NEC		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Gastrointestinal carcinoma	4	0
Hepatic neoplasms malignant		
Hepatic cancer	1	1
Hepatocellular carcinoma	1	0
Hepatobiliary neoplasms benign		
Haemangioma of liver	1	0
Hepatobiliary neoplasms malignancy unspecified		
Hepatic neoplasm	1	0
Hodgkin's disease NEC		
Hodgkin's disease	4	0
Islet cell neoplasms and APUDoma NEC		
Pancreatic neuroendocrine tumour	1	0
Kaposi's sarcomas		
Kaposi's sarcoma	1	0
Leukaemias NEC		
Leukaemia	7	1
Leukaemias acute NEC		
Acute leukaemia	2	0
Leukaemias chronic NEC		
Chronic leukaemia	1	0
Leukaemias chronic lymphocytic		
Chronic lymphocytic leukaemia	3	0
Leukaemias chronic myeloid		
Chronic myeloid leukaemia	1	0
Lip and oral cavity neoplasms malignant		
Lip and/or oral cavity cancer recurrent	1	0
Lymphomas unspecified NEC		
Lymphoma	48	1
Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)		
Histiocytic necrotising lymphadenitis	1	0
Mantle cell lymphomas		
Mantle cell lymphoma	2	0
Metastases to specified sites		
Metastases to bone	1	0
Metastases to liver	1	0
Metastases to lymph nodes	5	0
Metastases to unknown and unspecified sites		
Metastasis	1	0
Myelodysplastic syndromes		
Myelodysplastic syndrome	4	0
Myeloproliferative disorders (excl leukaemias)		
Essential thrombocythaemia	2	0
Neoplasms malignant site unspecified NEC		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	2	0
Neoplasm malignant	14	3
Second primary malignancy	1	0
Squamous cell carcinoma	5	0
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm	2	0
Neoplasm recurrence	1	0
Nervous system neoplasms benign NEC		
Cranial nerve neoplasm benign	1	0

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Neurilemmoma benign	1	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	5	0
Meningioma	1	0
Spinal cord neoplasm	1	1
Neuromas		
Acoustic neuroma	3	0
Neuroma	1	0
Non-Hodgkin's lymphomas NEC		
Non-Hodgkin's lymphoma	3	0
Ocular neoplasms benign		
Eye naevus	3	0
Ocular neoplasms malignancy unspecified		
Eyelid tumour	1	0
Oesophageal neoplasms malignant		
Oesophageal cancer metastatic	4	0
Oncologic complications and emergencies		
Cancer pain	1	0
Tumour haemorrhage	1	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified		
Tonsil cancer	4	0
Ovarian neoplasms malignant (excl germ cell)		
Ovarian cancer	1	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)		
Pancreatic carcinoma	4	0
Paraneoplastic syndromes NEC		
Paraneoplastic syndrome	2	0
Plasma cell myelomas		
POEMS syndrome	1	0
Plasma cell myeloma	2	0
Plasma cell neoplasms NEC		
Hypergammaglobulinaemia benign monoclonal	1	0
TEMPI syndrome	2	0
Prostatic neoplasms malignant		
Prostate cancer	4	0
Renal neoplasms malignant		
Clear cell renal cell carcinoma	1	0
Renal cancer	3	0
Reproductive neoplasms female benign NEC		
Benign hydatidiform mole	5	0
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC		
Bronchial carcinoma	1	0
Lung cancer metastatic	1	1
Lung neoplasm malignant	15	1
Salivary gland neoplasms unspecified malignancy		
Salivary gland neoplasm	2	0
Skin melanomas (excl ocular)		
Malignant melanoma	3	0
Metastatic malignant melanoma	1	0
Skin neoplasms benign		
Acrochordon	7	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Anogenital warts	7	0
Fibrous histiocytoma	1	0
Haemangioma of skin	7	0
Melanocytic naevus	10	0
Pyogenic granuloma	1	0
Seborrhoeic keratosis	2	0
Skin papilloma	22	0
Skin neoplasms malignant and unspecified (excl melanoma)		
Basal cell carcinoma	3	0
Bowen's disease	1	0
Neoplasm skin	3	0
Skin cancer	1	0
Squamous cell carcinoma of skin	1	0
Soft tissue neoplasms benign NEC		
Lipoma	7	0
Lymphangioma	1	0
Soft tissue sarcomas histology unspecified		
Sarcoma	1	0
Thyroid neoplasms malignant		
Anaplastic thyroid cancer	1	0
Huerthle cell carcinoma	1	0
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
Uterine neoplasms benign		
Uterine leiomyoma	18	0
Neoplasms SOC TOTAL	**394**	**12**

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Reaction Name	Total	Fatal
Nervous system disorders		
Abnormal reflexes		
Areflexia	9	0
Extensor plantar response	2	0
Hoffmann's sign	1	0
Hyperreflexia	5	0
Hyporeflexia	11	0
Reflexes abnormal	2	0
Abnormal sleep-related events		
Sleep paralysis	32	0
Absence seizures		
Petit mal epilepsy	32	0
Acute polyneuropathies		
Acute motor axonal neuropathy	1	0
Acute motor-sensory axonal neuropathy	1	0
Guillain-Barre syndrome	105	2
Miller Fisher syndrome	5	0
Subacute inflammatory demyelinating polyneuropathy	1	0
Alzheimer's disease (incl subtypes)		
Dementia Alzheimer's type	2	2
Autonomic nervous system disorders		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	16	0
Autonomic neuropathy	3	0
Horner's syndrome	2	0
Orthostatic intolerance	2	0
Central nervous system aneurysms and dissections		
Carotid artery dissection	2	0
Intracranial aneurysm	2	1
Vertebral artery dissection	1	0
Central nervous system haemorrhages and cerebrovascular accidents		
Basal ganglia haemorrhage	1	0
Basal ganglia infarction	1	0
Brain stem haemorrhage	4	3
Brain stem infarction	1	1
Brain stem stroke	3	0
Carotid artery occlusion	1	0
Carotid artery thrombosis	4	0
Cerebellar artery thrombosis	1	0
Cerebellar haemorrhage	3	0
Cerebellar infarction	3	0
Cerebellar ischaemia	1	0
Cerebellar stroke	8	1
Cerebral artery embolism	3	1
Cerebral artery occlusion	2	0
Cerebral artery thrombosis	5	0
Cerebral haemorrhage	65	15
Cerebral infarction	32	3
Cerebral ischaemia	1	0
Cerebral thrombosis	15	0
Cerebrovascular accident	503	20
Embolic stroke	8	0
Haemorrhage intracranial	16	4
Haemorrhagic cerebral infarction	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Haemorrhagic stroke	12	5
Internal capsule infarction	1	0
Intracranial haematoma	2	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	64	3
Lacunar infarction	4	0
Lacunar stroke	6	0
Lateral medullary syndrome	2	0
Pseudostroke	3	0
Ruptured cerebral aneurysm	1	0
Spinal cord infarction	1	0
Spinal stroke	1	0
Stroke in evolution	1	0
Subarachnoid haemorrhage	19	8
Thalamic infarction	1	0
Thrombotic stroke	6	1
Vertebrobasilar stroke	1	0
Central nervous system inflammatory disorders NEC		
Arachnoiditis	1	0
Gliosis	2	0
Central nervous system vascular disorders NEC		
Brain hypoxia	5	1
Carotid arteriosclerosis	1	0
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	1	0
Cerebral congestion	5	0
Cerebral small vessel ischaemic disease	4	0
Cerebrovascular disorder	3	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	58	5
Cerebral venous thrombosis	9	0
Superior sagittal sinus thrombosis	6	0
Transverse sinus thrombosis	3	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	2	0
Cervicobrachial syndrome	7	0
Choreiform movements		
Chorea	3	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	2	0
Demyelinating polyneuropathy	2	0
Diabetic neuropathy	1	0
Coma states		
Coma	18	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	23	0
Balance disorder	519	0
Cerebellar ataxia	1	0
Cerebellar syndrome	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Coordination abnormal	77	0
Dysdiadochokinesis	1	0
Dysstasia	76	0
Nystagmus	17	0
Cortical dysfunction NEC		
Alexia	2	0
Aphasia	106	0
Apraxia	1	0
Dysgraphia	4	0
Dyslexia	1	0
Dyspraxia	2	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	3	0
Visuospatial deficit	1	0
Cranial nerve disorders NEC		
Cranial nerve disorder	3	0
Cranial nerve paralysis	1	0
Dementia (excl Alzheimer's type)		
Dementia	19	0
Dementia with Lewy bodies	2	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	8	0
Clinically isolated syndrome	1	0
Demyelination	13	0
Neuromyelitis optica spectrum disorder	2	0
Disturbances in consciousness NEC		
Altered state of consciousness	14	0
Consciousness fluctuating	4	0
Depressed level of consciousness	56	0
Infant sedation	1	0
Lethargy	2576	0
Loss of consciousness	827	1
Postictal state	6	0
Sedation	9	0
Sedation complication	1	0
Somnolence	1224	0
Stupor	5	0
Syncope	2856	0
Disturbances in sleep phase rhythm		
Circadian rhythm sleep disorder	2	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	2	0
Non-24-hour sleep-wake disorder	1	0
Dyskinesias and movement disorders NEC		
Akathisia	7	0
Ballismus	1	0
Bradykinesia	26	0
Clumsiness	24	0
Dyskinesia	86	0
Extrapyramidal disorder	3	0
Fine motor skill dysfunction	13	0
Foetal movement disorder	7	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Hyperkinesia	4	0
Hypokinesia	114	0
Micrographia	1	0
Motor dysfunction	5	0
Movement disorder	73	0
Psychomotor hyperactivity	31	0
Synkinesis	2	0
Tardive dyskinesia	2	0
Dystonias		
Dystonia	17	0
Writer's cramp	1	0
Encephalitis NEC		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	7	0
Encephalopathies NEC		
Autoimmune encephalopathy	2	1
Encephalopathy	6	0
Hashimoto's encephalopathy	2	0
Posterior reversible encephalopathy syndrome	1	0
Eye movement disorders		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	7	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	2	0
VIth nerve disorder	1	0
VIth nerve paralysis	13	0
Facial cranial nerve disorders		
Bell's palsy	649	0
Facial nerve disorder	9	0
Facial paralysis	488	0
Facial paresis	108	0
Facial spasm	56	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	84	0
Glossopharyngeal nerve disorders		
Glossopharyngeal neuralgia	1	0
Headaches NEC		
Cervicogenic headache	3	0
Cluster headache	296	0
Cold-stimulus headache	37	0
Drug withdrawal headache	3	0
Exertional headache	10	0
External compression headache	2	0
Headache	30473	1
Medication overuse headache	2	0
New daily persistent headache	8	0
Occipital neuralgia	17	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	10	0
Sinus headache	403	0
Tension headache	638	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Thunderclap headache	25	0
Vascular headache	22	0
Hydrocephalic conditions		
Hydrocephalus	5	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain compression	2	0
Brain oedema	13	2
Idiopathic intracranial hypertension	12	0
Intracranial pressure increased	5	0
Intellectual disabilities		
Intellectual disability	4	0
Lumbar spinal cord and nerve root disorders		
Cauda equina syndrome	1	0
Sciatica	140	0
Memory loss (excl dementia)		
Amnesia	237	0
Memory impairment	260	0
Retrograde amnesia	1	0
Transient global amnesia	10	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	111	0
Cognitive linguistic deficit	1	0
Disturbance in attention	406	0
Mental impairment	64	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	44	0
Migraine	3571	0
Migraine with aura	235	0
Migraine without aura	22	0
Ophthalmic migraine	7	0
Retinal migraine	39	0
Typical aura without headache	9	0
Vestibular migraine	30	0
Mixed cranial nerve disorders		
Bulbar palsy	2	0
Mononeuropathies		
Carpal tunnel syndrome	36	0
Cubital tunnel syndrome	4	0
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	4	0
Nerve compression	32	0
Peripheral nerve lesion	2	0
Peroneal nerve palsy	21	0
Piriformis syndrome	2	0
Pudendal canal syndrome	3	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	3	0
Ulnar tunnel syndrome	2	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Motor neurone diseases		
Amyotrophic lateral sclerosis	1	0
Lower motor neurone lesion	2	0
Motor neurone disease	7	3
Progressive bulbar palsy	1	0
Upper motor neurone lesion	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	39	0
Multiple sclerosis relapse	26	0
Relapsing-remitting multiple sclerosis	1	0
Tumefactive multiple sclerosis	1	1
Muscle tone abnormal		
Drop attacks	2	0
Hypertonia	2	0
Hypotonia	40	0
Morvan syndrome	1	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	39	0
Narcolepsy and hypersomnia		
Cataplexy	3	0
Hypersomnia	126	0
Narcolepsy	7	0
Nervous system disorders NEC		
Central nervous system lesion	3	0
Cerebral disorder	3	0
Nervous system disorder	28	0
Neurotoxicity	4	0
Psychomotor skills impaired	1	0
Neurologic visual problems NEC		
Hemianopia	1	0
Hemianopia homonymous	2	0
Quadrantanopia	2	0
Tunnel vision	24	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Cerebrospinal fluid leakage	1	0
Clonus	5	0
Decerebrate posture	1	0
Decorticate posture	1	0
Dizziness	11479	0
Dizziness exertional	53	0
Dizziness postural	859	0
Drooling	27	0
Fontanelle bulging	2	0
Head discomfort	414	0
Hyporesponsive to stimuli	2	0
Inability to crawl	3	0
Infant irritability	10	0
Meningism	2	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Myoclonus	35	0
Neurological symptom	77	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	18	0
Presyncope	724	0
Sensory overload	5	0
Slow response to stimuli	4	0
Tongue biting	9	0
Unresponsive to stimuli	67	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	32	0
Muscle spasticity	20	0
Neuromuscular pain	3	0
Neuromuscular junction dysfunction		
Myasthenia gravis	17	0
Myasthenia gravis crisis	2	0
Myasthenic syndrome	1	0
Olfactory nerve disorders		
Anosmia	336	0
Hyposmia	19	0
Parosmia	341	0
Optic nerve disorders NEC		
Optic neuritis	45	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	15	0
Burning sensation	684	0
Burning sensation mucosal	2	0
Dysaesthesia	8	0
Formication	47	0
Hemianaesthesia	1	0
Hemihypoaesthesia	3	0
Hemiparaesthesia	5	0
Hyperaesthesia	126	0
Hypoaesthesia	3571	0
Lhermitte's sign	1	0
Paraesthesia	4879	0
Reversed hot-cold sensation	4	0
Synaesthesia	2	0
Vibration syndrome	3	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	22	0
Hemiparesis	71	0
Hemiplegia	50	0
Locked-in syndrome	1	0
Monoparesis	94	0
Monoplegia	103	0
Paralysis	159	1
Paraparesis	4	0
Paraplegia	3	0
Paresis	10	0
Quadriparesis	1	0
Quadriplegia	1	0
Parkinson's disease and parkinsonism		

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Reaction Name	Total	Fatal
Nervous system disorders		
Freezing phenomenon	18	0
Hypokinetic dysarthria	1	0
Parkinson's disease	4	0
Parkinsonian gait	1	0
Parkinsonian rest tremor	1	0
Parkinsonism	4	0
Reduced facial expression	11	0
Partial complex seizures		
Dreamy state	6	0
Focal dyscognitive seizures	6	0
Temporal lobe epilepsy	2	0
Partial simple seizures NEC		
Autonomic seizure	1	0
Peripheral neuropathies NEC		
Axonal neuropathy	2	0
Brachial plexopathy	2	0
Neuralgic amyotrophy	11	0
Neuritis	12	0
Neuropathy peripheral	165	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	13	0
Polyneuropathy	5	0
Small fibre neuropathy	4	0
Thoracic outlet syndrome	2	0
Seizures and seizure disorders NEC		
Atonic seizures	9	0
Change in seizure presentation	2	0
Clonic convulsion	6	0
Convulsions local	1	0
Convulsive threshold lowered	1	0
Epilepsy	178	0
Epileptic aura	2	0
Epileptic encephalopathy	2	0
Febrile convulsion	21	0
Idiopathic generalised epilepsy	1	0
Neonatal epileptic seizure	1	0
Partial seizures	30	0
Partial seizures with secondary generalisation	1	0
Post stroke seizure	1	0
Psychogenic seizure	11	0
Seizure	773	2
Seizure anoxic	3	0
Seizure cluster	7	0
Seizure like phenomena	4	0
Status epilepticus	41	0
Tonic clonic movements	7	0
Tonic convulsion	39	0
Tonic posturing	1	0
Sensory abnormalities NEC		
Ageusia	612	0
Allodynia	33	0
Aura	30	0
Central pain syndrome	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Complex regional pain syndrome	6	0
Dysgeusia	1337	0
Electric shock sensation	60	0
Hypergeusia	1	0
Hypogeusia	9	0
Intercostal neuralgia	3	0
Loss of proprioception	3	0
Morton's neuralgia	4	0
Neuralgia	743	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	8	0
Post herpetic neuralgia	18	0
Restless arm syndrome	4	0
Restless legs syndrome	165	0
Sensory disturbance	132	0
Sensory loss	118	0
Taste disorder	320	0
Visual perseveration	3	0
Sleep disturbances NEC		
Microsleep	1	0
Sleep deficit	13	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	249	0
Incoherent	15	0
Language disorder	2	0
Repetitive speech	5	0
Slow speech	24	0
Speech disorder	86	0
Speech disorder developmental	2	0
Spinal cord and nerve root disorders NEC		
Acquired syringomyelia	1	0
Myelopathy	1	0
Radiculitis brachial	18	0
Radiculopathy	8	0
Structural brain disorders NEC		
Brain injury	12	2
Cerebral ventricle dilatation	2	0
Hyperintensity in brain deep nuclei	1	0
Intracranial mass	1	0
White matter lesion	2	0
Transient cerebrovascular events		
Transient ischaemic attack	203	3
Tremor (excl congenital)		
Essential tremor	6	0
Head titubation	15	0
Resting tremor	4	0
Tremor	2189	0
Trigeminal disorders		
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	87	0
Trigeminal neuritis	3	0

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Reaction Name	Total	Fatal
Nervous system disorders	Nervous system disorders cont'd	
Vagus nerve disorders		
Vagus nerve disorder	1	0
Vocal cord paralysis	4	0
Vertigos NEC		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
Nervous system disorders SOC TOTAL	81665	93

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Reaction Name	Total	Fatal
Pregnancy conditions		
Abortion related conditions and complications		
Anembryonic gestation	3	0
Abortions not specified as induced or spontaneous		
Abortion	1	0
Abortion missed	7	0
Abortions spontaneous		
Abortion spontaneous	490	0
Abortion threatened	2	0
Amniotic fluid and cavity disorders of pregnancy NEC		
Amniorrhoea	2	0
Oligohydramnios	1	0
Foetal complications NEC		
Foetal cardiac disorder	1	0
Foetal distress syndrome	1	0
Foetal hypokinesia	13	0
Foetal conditions due to maternal conditions		
Maternal condition affecting foetus	1	0
Foetal growth complications		
Foetal growth restriction	8	1
Gestational age and weight conditions		
Low birth weight baby	1	0
Premature baby	8	1
Small for dates baby	1	0
Haemorrhagic complications of pregnancy		
Haemorrhage in pregnancy	3	0
Premature separation of placenta	3	0
Retroplacental haematoma	1	0
Subchorionic haematoma	3	0
Subchorionic haemorrhage	1	0
Hypertension associated disorders of pregnancy		
Pre-eclampsia	4	0
Labour onset and length abnormalities		
Induced labour	1	0
Premature delivery	1	0
Premature labour	9	0
Premature rupture of membranes	3	0
Threatened labour	1	0
Maternal complications of delivery NEC		
Retained placenta or membranes	2	0
Maternal complications of labour NEC		
Uterine contractions abnormal	1	0
Uterine hypertonus	8	0
Maternal complications of pregnancy NEC		
Biochemical pregnancy	4	0
Complication of pregnancy	1	0
Decidual cast	8	0
Ectopic pregnancy	15	0
Hyperemesis gravidarum	1	0
Morning sickness	17	0
Preterm premature rupture of membranes	3	0
Ruptured ectopic pregnancy	1	0
Somatic symptom disorder of pregnancy	3	0
Neonatal hepatobiliary disorders		

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Pregnancy conditions Pregnancy conditions cont'd		
Jaundice neonatal	1	0
Normal newborn status		
Normal newborn	2	0
Normal pregnancy, labour and delivery		
Labour pain	1	0
Live birth	8	0
Pregnancy	35	0
Term birth	2	0
Uterine contractions during pregnancy	6	0
Placental abnormalities (excl neoplasms)		
Foetal vascular malperfusion	2	0
Placental calcification	1	0
Placental disorder	2	0
Placental insufficiency	1	0
Small size placenta	2	0
Postpartum complications NEC		
Postpartum haemorrhage	5	0
Pregnancy complicated by maternal disorders		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
Stillbirth and foetal death		
Foetal death	2	2
Stillbirth	10	10
Umbilical cord complications		
Umbilical cord abnormality	1	0
Umbilical cord thrombosis	1	0
Unintended pregnancies		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	3	0
Pregnancy on oral contraceptive	2	0
Pregnancy with contraceptive device	2	0
Pregnancy with implant contraceptive	1	0
Unintended pregnancy	4	0
Unwanted pregnancy	1	0
Pregnancy conditions SOC TOTAL	**734**	**14**

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Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Device electrical issues		
Electromagnetic interference	1	0
Device issues NEC		
Device connection issue	1	0
Device failure	1	0
Device issue	3	0
Device malfunction events NEC		
Device infusion issue	1	0
Device malfunction	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	21	0
Thrombosis in device	16	0
Undersensing	1	0
Device physical property and chemical issues		
Device breakage	1	0
Device defective	9	0
Device kink	1	0
Needle issue	3	0
Manufacturing materials issues		
Manufacturing materials contamination	1	0
Product contamination and sterility issues		
Product contamination	17	0
Product contamination physical	11	0
Product packaging issues		
Packaging design issue	1	0
Product closure issue	1	0
Product physical issues		
Liquid product physical issue	12	0
Product after taste	3	0
Product deposit	1	0
Product odour abnormal	3	0
Product physical issue	2	0
Product taste abnormal	9	0
Product quality issues NEC		
Product complaint	2	0
Product origin unknown	5	0
Product supply and availability issues		
Product availability issue	1	0
null SOC TOTAL	**131**	**0**

Case Series Drug Analysis Print

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Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
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Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	28	0
Behaviour disorder	2	0
Breath holding	7	0
Staring	8	0
Adjustment disorders		
Adjustment disorder	1	0
Adjustment disorder with depressed mood	5	0
Affect alterations NEC		
Affect lability	16	0
Constricted affect	8	0
Flat affect	12	0
Inappropriate affect	23	0
Amnestic symptoms		
Paramnesia	7	0
Anxiety disorders NEC		
Anxiety disorder	2	0
Generalised anxiety disorder	3	0
Neurosis	1	0
Anxiety symptoms		
Agitation	100	0
Anxiety	1124	0
Immunisation stress-related response	4	0
Nervousness	218	0
Stress	144	0
Tension	47	0
Attention deficit and disruptive behaviour disorders		
Attention deficit hyperactivity disorder	7	0
Behaviour and socialisation disturbances		
Aggression	18	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	3	0
Indifference	7	0
Paranoia	31	0
Personality change	7	0
Social avoidant behaviour	6	0
Soliloquy	2	0
Suspiciousness	1	0
Bipolar disorders		
Bipolar I disorder	2	0
Bipolar disorder	5	0
Cognitive and attention disorders and disturbances NEC		
Daydreaming	9	0
Distractibility	4	0
Mental fatigue	252	0
Communications disorders		
Communication disorder	8	0
Mutism	4	0
Speech sound disorder	1	0
Confusion and disorientation		
Confusional state	1078	0
Disorientation	332	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Decreased physical activity levels		
Catatonia	1	0
Deliria		
Delirium	154	1
Delusional symptoms		
Delusion	19	0
Depressive disorders		
Agitated depression	6	0
Depression	434	0
Depression suicidal	20	0
Major depression	15	0
Mixed anxiety and depressive disorder	4	0
Dissociative states		
Depersonalisation/derealisation disorder	13	0
Dissociation	40	0
Dissociative amnesia	4	0
Dissociative disorder	2	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	30	0
Insomnia	2005	0
Middle insomnia	34	0
Terminal insomnia	35	0
Dyssomnias		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	271	0
Eating disorders NEC		
Bulimia nervosa	1	0
Eating disorder	16	0
Selective eating disorder	1	0
Emotional and mood disturbances NEC		
Anger	48	0
Dysphoria	3	0
Emotional disorder	76	0
Emotional distress	65	0
Emotional poverty	2	0
Euphoric mood	51	0
Frustration tolerance decreased	2	0
Irritability	240	0
Mood altered	67	0
Morose	1	0
Factitious disorders		
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Agoraphobia	2	0
Claustrophobia	1	0
Fear	34	0
Fear of death	2	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	6	0
Osmophobia	1	0
Performance fear	1	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Phobia	3	0
Phonophobia	3	0
Social anxiety disorder	2	0
Social fear	1	0
Fluctuating mood symptoms		
Mood swings	174	0
Hallucinations (excl sleep-related)		
Hallucination	262	0
Hallucination, auditory	23	0
Hallucination, olfactory	15	0
Hallucination, tactile	1	0
Hallucination, visual	33	0
Hallucinations, mixed	4	0
Increased physical activity levels		
Restlessness	178	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Social (pragmatic) communication disorder	1	0
Learning disorders		
Learning disability	1	0
Learning disorder	1	0
Reading disorder	1	0
Mental disorders NEC		
Mental disorder	24	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
Mood alterations with depressive symptoms		
Anhedonia	3	0
Decreased interest	12	0
Depressed mood	461	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	5	0
Feelings of worthlessness	2	0
Negative thoughts	3	0
Psychomotor retardation	2	0
Sense of a foreshortened future	3	0
Tearfulness	50	0
Mood alterations with manic symptoms		
Hypomania	2	0
Mania	11	0
Mood disorders NEC		
Affective disorder	4	0
Apathy	39	0
Boredom	1	0
Laziness	3	0
Listless	26	0
Mood disorder due to a general medical condition	1	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	4	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive symptom	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Orgasmic disorders and disturbances		
Anorgasmia	5	0
Female orgasmic disorder	2	0
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
Panic attacks and disorders		
Limited symptom panic attack	1	0
Panic attack	271	0
Panic disorder	10	0
Panic reaction	32	0
Paraphilias and paraphilic disorders		
Transvestism	1	0
Parasomnias		
Abnormal dreams	213	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	239	0
Parasomnia	5	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	29	0
Somnambulism	10	0
Perception disturbances NEC		
Autoscopy	20	0
Deja vu	3	0
Derealisation	14	0
Flashback	4	0
Illusion	6	0
Near death experience	1	0
Time perception altered	2	0
Personality disorders NEC		
Personality disorder	1	0
Self esteem decreased	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	5	0
Psychiatric elimination disorders		
Enuresis	31	0
Psychiatric symptoms NEC		
Helplessness	1	0
Hypervigilance	9	0
Psychiatric symptom	13	0
Psychological trauma	4	0
Trance	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	34	0
Schizophrenia NEC		
Schizophrenia	2	0
Sexual and gender identity disorders NEC		
Gender dysphoria	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Sexual arousal disorders		
Disturbance in sexual arousal	4	0
Sexual inhibition	1	0
Sexual desire disorders		
Hypersexuality	1	0
Libido decreased	20	0
Libido disorder	2	0
Libido increased	8	0
Loss of libido	22	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	2	0
Sleep disorders NEC		
Sleep disorder	290	0
Sleep disorder due to general medical condition, insomnia type	5	0
Somatic symptom disorders		
Conversion disorder	34	0
Habit cough	22	0
Somatic symptom disorder	2	0
Vomiting psychogenic	1	0
Speech and language usage disturbances		
Disorganised speech	10	0
Logorrhoea	2	0
Speech articulation and rhythm disturbances		
Dysphemia	28	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
Stereotypies and automatisms		
Automatism	1	0
Bruxism	16	0
Head banging	13	0
Stereotypy	1	0
Stress disorders		
Burnout syndrome	2	0
Post-traumatic stress disorder	6	0
Substance related and addictive disorders		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	5	0
Dependence	1	0
Nicotine dependence	2	0
Suicidal and self-injurious behaviour		
Completed suicide	3	3
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	55	0
Suicide attempt	9	0
Suicide threat	2	0
Thinking disturbances		
Bradyphrenia	45	0
Flight of ideas	1	0
Intrusive thoughts	8	0
Morbid thoughts	1	0
Tachyphrenia	8	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Thinking abnormal	22	0
Thought blocking	3	0
Tic disorders		
Tic	20	0
Psychiatric disorders SOC TOTAL	**10306**	**4**

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Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
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Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Bladder discomfort	4	0
Bladder irritation	14	0
Bladder pain	36	0
Bladder spasm	2	0
Dysuria	60	0
Incontinence	47	0
Lower urinary tract symptoms	3	0
Micturition disorder	2	0
Micturition urgency	55	0
Mixed incontinence	1	0
Pollakiuria	164	0
Stress urinary incontinence	2	0
Urethral pain	8	0
Urge incontinence	3	0
Urinary hesitation	3	0
Urinary incontinence	79	0
Urinary retention	56	0
Urine flow decreased	19	0
Bladder disorders NEC		
Bladder dilatation	1	0
Bladder disorder	14	0
Bladder fibrosis	1	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	4	0
Bladder infections and inflammations		
Cystitis haemorrhagic	1	0
Cystitis interstitial	6	0
Cystitis noninfective	1	0
Bladder neoplasms		
Bladder cyst	1	0
Genital and urinary tract disorders NEC		
Genitourinary symptom	2	0
Urinary tract disorder	4	0
Urinary tract obstruction	1	0
Glomerulonephritis and nephrotic syndrome		
Anti-glomerular basement membrane disease	1	0
Focal segmental glomerulosclerosis	1	0
Glomerulonephritis membranous	1	0
Glomerulonephritis minimal lesion	8	0
Glomerulonephritis rapidly progressive	2	0
Goodpasture's syndrome	1	0
IgA nephropathy	4	0
Nephrotic syndrome	22	0
Myoneurogenic bladder disorders		
Automatic bladder	1	0
Bladder dysfunction	8	0
Hypertonic bladder	6	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	3	0
Neurogenic bladder	2	0
Nephritis NEC		
Lupus nephritis	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Renal & urinary disorders (Renal & urinary disorders cont'd)		
Nephritis	3	0
Tubulointerstitial nephritis	3	0
Nephropathies and tubular disorders NEC		
Nephropathy	1	0
Renal disorders NEC		
Kidney fibrosis	1	0
Renal disorder	12	1
Renal haemorrhage	1	0
Renal mass	1	0
Renal failure and impairment		
Acute kidney injury	59	4
Anuria	3	0
Chronic kidney disease	6	0
Oliguria	1	0
Renal failure	26	1
Renal impairment	36	0
Renal injury	3	0
Renal failure complications		
Azotaemia	1	0
Renal lithiasis		
Nephrolithiasis	12	0
Renal neoplasms		
Renal cyst	1	0
Renal obstructive disorders		
Hydronephrosis	2	0
Renal structural abnormalities and trauma		
Kidney enlargement	1	0
Kidney small	2	0
Renal vascular and ischaemic conditions		
Renal aneurysm	1	0
Renal infarct	4	0
Renal tubular necrosis	2	0
Renal vasculitis	2	1
Structural and obstructive urethral disorders (excl congenital)		
Urethral stenosis	1	0
Ureteric disorders NEC		
Ureteric stenosis	1	0
Urinary abnormalities		
Albuminuria	1	0
Chromaturia	69	0
Haematuria	55	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	13	0
Urine abnormality	13	0
Urine odour abnormal	11	0
Urinary tract lithiasis (excl renal)		
Calculus bladder	1	0
Calculus urinary	1	0
Urinary tract signs and symptoms NEC		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	31	1

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Reaction Name	Total	Fatal
Renal & urinary disorders Renal & urinary disorders cont'd		
Nocturia	3	0
Polyuria	9	0
Renal colic	5	0
Renal pain	369	0
Urinary tract discomfort	2	0
Urinary tract pain	6	0
Renal & urinary disorders SOC TOTAL	**1437**	**8**

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Benign and malignant breast neoplasms		
Breast cyst	18	0
Breast disorders NEC		
Breast atrophy	1	0
Breast disorder	4	0
Breast enlargement	32	0
Breast mass	152	0
Fibrocystic breast disease	1	0
Gynaecomastia	7	0
Mastoptosis	1	0
Nipple disorder	1	0
Breast infections and inflammations		
Breast inflammation	6	0
Nipple inflammation	3	0
Breast signs and symptoms		
Breast discharge	5	0
Breast discomfort	15	0
Breast engorgement	11	0
Breast haematoma	1	0
Breast oedema	9	0
Breast pain	878	0
Breast swelling	196	0
Breast tenderness	107	0
Nipple pain	47	1
Nipple swelling	4	0
Cervix disorders NEC		
Cervical dysplasia	3	0
Cervix disorder	1	0
Cervix haemorrhage uterine	5	0
Ectropion of cervix	5	0
Cervix infections and inflammations		
Cervix inflammation	1	0
Cervix neoplasms		
Cervical polyp	2	0
Erection and ejaculation conditions and disorders		
Ejaculation disorder	3	0
Ejaculation failure	3	0
Erectile dysfunction	78	0
Erection increased	4	0
Organic erectile dysfunction	14	0
Painful ejaculation	1	0
Spontaneous ejaculation	2	0
Spontaneous penile erection	2	0
Fallopian tube and ovary infections and inflammations		
Noninfective oophoritis	6	0
Lactation disorders		
Breast milk discolouration	4	0
Breast milk odour abnormal	2	0
Galactorrhoea	5	0
Galactostasis	1	0
Lactation disorder	11	0
Lactation puerperal increased	6	0
Suppressed lactation	50	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Menopausal effects NEC		
Artificial menopause	1	0
Menopausal disorder	1	0
Menopausal symptoms	47	0
Menopause delayed	1	0
Premature menopause	25	0
Menopausal effects on the genitourinary tract		
Atrophic vulvovaginitis	2	0
Postmenopausal haemorrhage	117	0
Menstruation and uterine bleeding NEC		
Abnormal uterine bleeding	8	0
Abnormal withdrawal bleeding	3	0
Bleeding anovulatory	1	0
Dysmenorrhoea	3351	0
Intermenstrual bleeding	1326	0
Menstrual discomfort	36	0
Menstrual disorder	2322	0
Menstruation irregular	4119	0
Premenstrual dysphoric disorder	14	0
Premenstrual headache	13	0
Premenstrual pain	152	0
Premenstrual syndrome	142	0
Retrograde menstruation	2	0
Withdrawal bleed	16	0
Menstruation with decreased bleeding		
Amenorrhoea	736	0
Hypomenorrhoea	762	0
Menstruation delayed	5784	0
Oligomenorrhoea	234	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	6388	0
Menometrorrhagia	21	0
Polymenorrhoea	1052	0
Ovarian and fallopian tube cysts and neoplasms		
Haemorrhagic ovarian cyst	3	0
Ovarian cyst	32	0
Ovarian cyst ruptured	2	0
Polycystic ovaries	51	0
Ovarian and fallopian tube disorders NEC		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian enlargement	1	0
Ovarian failure	1	0
Ovarian haemorrhage	8	0
Ovarian hyperstimulation syndrome	1	0
Ovarian mass	2	0
Ovarian necrosis	1	0
Ovulation disorder	4	0
Ovulation pain	85	0
Premature ovulation	4	0
Superovulation	1	0
Pelvic prolapse conditions		
Vaginal prolapse	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders (Reproductive & breast disorders cont'd)		
Pelvis and broad ligament disorders NEC		
Adnexa uteri mass	1	0
Adnexa uteri pain	72	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic fluid collection	1	0
Pelvic haemorrhage	22	0
Penile and scrotal infections and inflammations		
Balanoposthitis	5	0
Penile disorders NEC (excl erection and ejaculation)		
Foreskin oedema	1	0
Penile blister	1	0
Penile discharge	1	0
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	3	0
Penile oedema	1	0
Penile pain	2	0
Penile rash	1	0
Penile size reduced	1	0
Penile swelling	6	0
Penis disorder	13	0
Peyronie's disease	1	0
Prostate and seminal vesicles infections and inflammations		
Prostatitis	5	0
Prostatic neoplasms and hypertrophy		
Benign prostatic hyperplasia	2	0
Prostatic signs, symptoms and disorders NEC		
Prostatic pain	1	0
Prostatomegaly	3	0
Reproductive tract disorders NEC (excl neoplasms)		
Genital erosion	1	0
Genital haemorrhage	25	0
Genital hypoaesthesia	2	0
Genital lesion	2	0
Genital paraesthesia	1	0
Genital ulceration	8	0
Perineal ulceration	1	0
Reproductive tract infections and inflammations NEC		
Genital tract inflammation	1	0
Reproductive tract signs and symptoms NEC		
Genital burning sensation	3	0
Genital discolouration	1	0
Genital erythema	1	0
Genital pain	7	0
Genital rash	6	0
Genital swelling	5	0
Pelvic discomfort	6	0
Pelvic pain	134	0
Perineal pain	3	0
Perineal rash	1	0
Pruritus genital	8	0
Scrotal disorders NEC		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	2	0
Scrotal exfoliation	2	0
Scrotal pain	22	0
Scrotal swelling	6	0
Scrotum erosion	1	0
Varicocele	2	0
Sexual function and fertility disorders NEC		
Dyspareunia	7	0
Infertility	18	0
Infertility female	5	0
Infertility male	1	0
Sexual dysfunction	10	0
Spermatogenesis and semen disorders		
Aspermia	1	0
Haematospermia	8	0
Semen discolouration	1	0
Testicular and epididymal disorders NEC		
Testicular atrophy	1	0
Testicular disorder	4	0
Testicular oedema	1	0
Testicular pain	74	0
Testicular swelling	14	0
Testicular torsion	1	0
Testis discomfort	3	0
Testicular and epididymal neoplasms		
Testicular cyst	1	0
Uterine disorders NEC		
Adenomyosis	11	0
Endometrial thickening	4	0
Endometriosis	98	0
Uterine haemorrhage	49	0
Uterine pain	19	0
Uterine infections and inflammations (excl cervix)		
Uterine inflammation	1	0
Uterine neoplasms		
Uterine polyp	6	0
Uterine tone disorders		
Uterine spasm	42	0
Vaginal and vulval infections and inflammations		
Vulvovaginal inflammation	2	0
Vulvovaginal cysts and neoplasms		
Bartholin's cyst	2	0
Vaginal cyst	8	0
Vaginal polyp	1	0
Vulva cyst	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	1819	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	4	0
Vulval disorder	2	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Reproductive & breast disorders Reproductive & breast disorders cont'd		
Vulval haemorrhage	34	0
Vulval ulceration	8	0
Vulvovaginal ulceration	6	0
Vulvovaginal signs and symptoms		
Clitoral engorgement	1	0
Coital bleeding	8	0
Labia enlarged	2	0
Vaginal discharge	89	0
Vaginal lesion	1	0
Vaginal odour	4	0
Vaginal oedema	1	0
Vulval eczema	1	0
Vulval oedema	2	0
Vulvovaginal burning sensation	9	0
Vulvovaginal discomfort	2	0
Vulvovaginal dryness	6	0
Vulvovaginal erythema	3	0
Vulvovaginal pain	33	0
Vulvovaginal pruritus	11	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	5	0
Reproductive & breast disorders SOC TOTAL	**31433**	**1**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Apnoea	7	0
Apnoeic attack	1	0
Dyspnoea	7042	5
Dyspnoea at rest	11	0
Dyspnoea exertional	49	1
Grunting	1	0
Hyperventilation	67	0
Hypopnoea	133	0
Hypoventilation	1	0
Irregular breathing	29	0
Mouth breathing	7	0
Nocturnal dyspnoea	2	0
Obstructive sleep apnoea syndrome	1	0
Orthopnoea	4	0
Respiration abnormal	74	0
Respiratory arrest	23	0
Respiratory depression	1	0
Respiratory distress	20	0
Sleep apnoea syndrome	17	0
Tachypnoea	33	0
Bronchial conditions NEC		
Bronchial secretion retention	4	0
Bronchiectasis	16	0
Bronchospasm and obstruction		
Asthma	440	0
Asthma late onset	3	0
Bronchospasm	19	0
Chronic obstructive pulmonary disease	29	1
Cough variant asthma	8	0
Obstructive airways disorder	14	0
Reversible airways obstruction	1	0
Wheezing	488	0
Conditions associated with abnormal gas exchange		
Asphyxia	2	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	36	2
Respiratory acidosis	2	0
Coughing and associated symptoms		
Allergic cough	9	0
Atopic cough	1	0
Cough	3032	1
Cough decreased	2	0
Haemoptysis	76	0
Productive cough	200	0
Sputum discoloured	11	0
Sputum increased	4	0
Diaphragmatic disorders		
Acquired diaphragmatic eventration	1	0
Diaphragm muscle weakness	1	0
Diaphragmatic disorder	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		
Laryngeal disorder	1	0
Reflux laryngitis	3	0
Vocal cord disorder	2	0
Vocal cord dysfunction	3	0
Laryngeal spasm, oedema and obstruction		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	4	0
Laryngospasm	3	0
Stridor	28	0
Lower respiratory tract inflammatory and immunologic conditions		
Alveolitis	1	0
Autoimmune lung disease	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonitis	36	2
Pulmonary sarcoidosis	3	0
Lower respiratory tract signs and symptoms		
Hiccups	36	0
Increased bronchial secretion	3	0
Increased viscosity of bronchial secretion	1	0
Lung hyperinflation	2	0
Lung opacity	4	0
Pleuritic pain	27	0
Pulmonary haemorrhage	1	0
Pulmonary pain	122	0
Rales	7	0
Respiratory fremitus	1	0
Mediastinal disorders		
Mediastinal mass	1	0
Pulmonary hilum mass	1	0
Nasal congestion and inflammations		
Nasal congestion	342	0
Nasal inflammation	5	0
Rhinitis allergic	28	0
Nasal disorders NEC		
Epistaxis	1112	0
Intranasal hypoaesthesia	2	0
Intranasal paraesthesia	1	0
Nasal crusting	2	0
Nasal disorder	4	0
Nasal dryness	36	0
Nasal mucosal discolouration	1	0
Nasal odour	7	0
Nasal oedema	8	0
Nasal polyps	2	0
Nasal pruritus	13	0
Nasal ulcer	3	0
Neonatal hypoxic conditions		
Dry lung syndrome	1	0
Gasping syndrome	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Infantile apnoea	2	0
Paranasal sinus disorders (excl infections and neoplasms)		
Allergic sinusitis	3	0
Paranasal sinus inflammation	5	0
Sinonasal obstruction	15	0
Sinus congestion	74	0
Sinus disorder	8	0
Parenchymal lung disorders NEC		
Atelectasis	5	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	3	0
Interstitial lung disease	11	0
Lung consolidation	6	0
Lung infiltration	2	1
Organising pneumonia	2	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	11	0
Pulmonary toxicity	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Hyperactive pharyngeal reflex	1	0
Pharyngeal enanthema	1	0
Pharyngeal erythema	10	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	40	0
Pharyngeal inflammation	4	0
Pharyngeal lesion	1	0
Pharyngeal mass	1	0
Pharyngeal oedema	15	0
Pharyngeal paraesthesia	57	0
Pharyngeal swelling	303	0
Pharyngeal ulceration	19	0
Tonsillar erythema	14	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	99	0
Tonsillar inflammation	4	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
Pleural infections and inflammations		
Pleurisy	41	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	44	0
Pneumothorax	14	0
Pneumothorax spontaneous	5	0
Pulmonary hypertensions		
Pulmonary hypertension	3	0
Pulmonary oedemas		
Acute respiratory distress syndrome	3	1
Pulmonary congestion	20	0
Pulmonary oedema	25	2
Pulmonary thrombotic and embolic conditions		
Pulmonary artery thrombosis	2	0
Pulmonary embolism	561	41

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Pulmonary infarction	7	0
Pulmonary thrombosis	13	1
Respiratory failures (excl neonatal)		
Acute respiratory failure	3	1
Respiratory failure	15	2
Respiratory signs and symptoms NEC		
Allergic respiratory symptom	6	0
Diaphragmalgia	10	0
Nasal flaring	1	0
Painful respiration	19	1
Pleural rub	1	0
Respiratory symptom	21	0
Suffocation feeling	2	0
Use of accessory respiratory muscles	2	0
Respiratory tract disorders NEC		
Allergic respiratory disease	1	0
Aspiration	4	0
Lung disorder	12	0
Pulmonary mass	6	0
Respiratory disorder	16	1
Respiratory tract congestion	5	0
Respiratory tract haemorrhage	2	0
Respiratory tract inflammation	2	0
Respiratory tract irritation	9	0
Respiratory tract oedema	4	0
Thoracic musculoskeletal disorders		
Respiratory muscle weakness	2	0
Tracheal disorders (excl infections and neoplasms)		
Tracheal disorder	1	0
Tracheal pain	2	0
Upper respiratory tract neoplasms		
Tonsillar cyst	1	0
Upper respiratory tract signs and symptoms		
Aphonia	148	0
Catarrh	34	0
Choking	21	0
Choking sensation	7	0
Dry throat	188	0
Dysphonia	189	0
Increased upper airway secretion	6	0
Increased viscosity of upper respiratory secretion	37	0
Laryngeal pain	1	0
Nasal discharge discolouration	4	0
Nasal discomfort	59	0
Nasal obstruction	3	0
Oropharyngeal blistering	11	0
Oropharyngeal discolouration	1	0
Oropharyngeal discomfort	71	0
Oropharyngeal pain	3314	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	55	0
Rhinalgia	15	0
Rhinorrhoea	1093	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Sinus pain	252	0
Sneezing	469	0
Snoring	8	0
Throat clearing	8	0
Throat irritation	270	0
Throat lesion	1	0
Throat tightness	294	0
Upper airway obstruction	3	0
Upper respiratory tract congestion	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	16	0
Yawning	31	0
Vascular pulmonary disorders NEC		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	**22013**	**63**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Skin disorders		
Acnes		
Acne	222	0
Acne cystic	28	0
Dermatitis acneiform	13	0
Oil acne	1	0
Alopecias		
Alopecia	486	0
Alopecia areata	81	0
Alopecia totalis	4	0
Alopecia universalis	3	0
Androgenetic alopecia	2	0
Diffuse alopecia	4	0
Hypotrichosis	3	0
Lichen planopilaris	2	0
Madarosis	9	0
Angioedemas		
Angioedema	286	0
Circumoral oedema	1	0
Circumoral swelling	1	0
Idiopathic angioedema	1	0
Apocrine and eccrine gland disorders		
Anhidrosis	2	0
Bromhidrosis	1	0
Cold sweat	891	0
Hidradenitis	5	0
Hyperhidrosis	2740	0
Hypohidrosis	3	0
Milia	2	0
Miliaria	120	0
Night sweats	970	0
Sweat discolouration	1	0
Bullous conditions		
Autoimmune blistering disease	1	0
Blister	558	0
Blister rupture	1	0
Blood blister	37	0
Dermatitis bullous	19	0
Erythema multiforme	45	0
Fracture blisters	1	0
Herpes gestationis	1	0
Mucous membrane pemphigoid	1	0
Pemphigoid	33	0
Pemphigus	9	0
Stevens-Johnson syndrome	7	0
Toxic epidermal necrolysis	2	1
Connective tissue disorders		
Chronic cutaneous lupus erythematosus	3	0
Dermatomyositis	12	0
Subacute cutaneous lupus erythematosus	3	0
Dermal and epidermal conditions NEC		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	2	0
Dry skin	307	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Koebner phenomenon	1	0
Macule	5	0
Neutrophilic dermatosis	1	0
Pain of skin	351	0
Papule	120	0
Pathergy reaction	1	0
Scab	28	0
Scar discomfort	1	0
Scar pain	20	0
Sensitive skin	238	0
Shagreen skin	1	0
Skin burning sensation	274	0
Skin degenerative disorder	1	0
Skin discolouration	169	0
Skin discomfort	6	0
Skin disorder	37	0
Skin fissures	11	0
Skin indentation	3	0
Skin induration	5	0
Skin lesion	53	0
Skin lesion inflammation	1	0
Skin necrosis	3	0
Skin odour abnormal	27	0
Skin plaque	4	0
Skin reaction	175	0
Skin sensitisation	45	0
Skin swelling	117	0
Skin texture abnormal	2	0
Skin tightness	30	0
Skin warm	372	0
Skin weeping	18	0
Sticky skin	3	0
Target skin lesion	3	0
Transient acantholytic dermatosis	1	0
Yellow skin	29	0
Dermatitis and eczema		
Autoimmune dermatitis	2	0
Dermatitis	170	0
Dermatitis allergic	308	0
Dermatitis atopic	65	0
Dermatitis contact	27	0
Dermatitis diaper	4	0
Dyshidrotic eczema	32	0
Eczema	442	0
Eczema asteatotic	17	0
Eczema infantile	1	0
Eczema nummular	8	0
Eczema vesicular	1	0
Eczema weeping	8	0
Hand dermatitis	5	0
Intertrigo	1	0
Neurodermatitis	4	0
Perioral dermatitis	3	0

Case Series Drug Analysis Print

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Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Seborrhoeic dermatitis	9	0
Skin irritation	160	0
Stasis dermatitis	2	0
Dermatitis ascribed to specific agent		
Drug eruption	35	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	3	0
Palmar-plantar erythrodysaesthesia syndrome	3	0
Toxic skin eruption	2	0
Erythemas		
Erythema	2533	0
Palmar erythema	4	0
Pernio-like erythema	1	0
Vancomycin infusion reaction	2	0
Exfoliative conditions		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	6	0
Exfoliative rash	26	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	153	0
Granulomatous and deep cutaneous inflammatory conditions		
Cutaneous sarcoidosis	1	0
Granuloma annulare	8	0
Necrobiosis lipoidica diabeticorum	1	0
Hyperkeratoses		
Hyperkeratosis	2	0
Keratosis pilaris	3	0
Lichenoid keratosis	4	0
Hyperpigmentation disorders		
Argyria	1	0
Chloasma	2	0
Ephelides	1	0
Skin hyperpigmentation	7	0
Solar lentigo	4	0
Hypertrichoses		
Hirsutism	2	0
Hypertrichosis	2	0
Hypopigmentation disorders		
Skin depigmentation	5	0
Skin hypopigmentation	1	0
Vitiligo	27	0
Lipodystrophies		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
Nail and nail bed conditions (excl infections and infestations)		
Ingrowing nail	2	0
Nail discolouration	12	0
Nail disorder	7	0
Nail growth abnormal	1	0
Nail pigmentation	2	0
Nail ridging	3	0
Onychalgia	10	0
Onychoclasis	6	0

Case Series Drug Analysis Print

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Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Onychomadesis	3	0
Splinter haemorrhages	4	0
Panniculitides		
Erythema nodosum	35	0
Panniculitis	3	0
Papulosquamous conditions		
Erythema annulare	2	0
Lichen planus	28	0
Lichen sclerosus	12	0
Parapsoriasis	9	0
Pityriasis alba	1	0
Pityriasis rosea	145	0
Pityriasis rubra pilaris	1	0
Photosensitivity and photodermatosis conditions		
Actinic prurigo	1	0
Photosensitivity reaction	72	0
Polymorphic light eruption	4	0
Solar dermatitis	2	0
Pigmentation changes NEC		
Haemosiderin stain	1	0
Pigmentation disorder	18	0
Pilar disorders NEC		
Hair colour changes	11	0
Hair disorder	1	0
Hair growth abnormal	14	0
Hair texture abnormal	7	0
Piloerection	29	0
Pseudofolliculitis	3	0
Trichorrhexis	3	0
Pruritus NEC		
Itching scar	10	0
Polymorphic eruption of pregnancy	1	0
Pruritus	6480	0
Psoriatic conditions		
Dermatitis psoriasiform	6	0
Guttate psoriasis	25	0
Nail psoriasis	3	0
Palmoplantar pustulosis	2	0
Psoriasis	266	0
Pustular psoriasis	3	0
Rebound psoriasis	2	0
Purpura and related conditions		
Ecchymosis	1	0
Henoch-Schonlein purpura	16	0
Petechiae	164	0
Purpura	63	0
Pustular conditions		
Acute generalised exanthematous pustulosis	2	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	8	0
Rash	6796	1
Rash erythematous	1475	0
Rash macular	590	0

Case Series Drug Analysis Print

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Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash maculo-papular	69	0
Rash morbilliform	50	0
Rash papular	409	0
Rash pruritic	1442	0
Rash scarlatiniform	1	0
Rash vesicular	91	0
Systemic lupus erythematosus rash	9	0
Rosaceas		
Erythematotelangiectatic rosacea	1	0
Papulopustular rosacea	1	0
Rosacea	40	0
Scaly conditions		
Dandruff	5	0
Pityriasis	32	0
Sebaceous gland disorders		
Sebaceous glands overactivity	1	0
Seborrhoea	15	0
Skin and subcutaneous conditions NEC		
Cellulite	2	0
Cutaneous symptom	6	0
Reactive perforating collagenosis	1	0
Skin mass	31	0
Skin and subcutaneous tissue ulcerations		
Ischaemic skin ulcer	1	0
Mucocutaneous ulceration	1	0
Pyoderma gangrenosum	2	0
Scleroderma associated digital ulcer	1	0
Skin erosion	31	0
Skin ulcer	23	0
Skin cysts and polyps		
Dermal cyst	21	0
Skin dystrophies		
Keloid scar	3	0
Skin wrinkling	4	0
Skin haemorrhages		
Haemorrhage subcutaneous	15	0
Skin haemorrhage	24	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	2	0
Skin hypoplasias and atrophies		
Skin atrophy	3	0
Skin striae	8	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	3	0
Needle track marks	5	0
Skin preneoplastic conditions NEC		
Actinic keratosis	1	0
Skin vascular conditions NEC		
Angiodermatitis	2	0
Skin oedema	5	0
Skin vasculitides		
Capillaritis	4	0
Cutaneous vasculitis	16	0

Case Series Drug Analysis Print

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Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Hypersensitivity vasculitis	1	0
Vasculitic rash	22	0
Skin vasomotor conditions		
Livedo reticularis	30	0
Telangiectasia and related conditions		
Spider naevus	1	0
Telangiectasia	1	0
Urticarias		
Chronic spontaneous urticaria	15	0
Cold urticaria	11	0
Idiopathic urticaria	4	0
Mechanical urticaria	18	0
Solar urticaria	3	0
Urticaria	2359	0
Urticaria cholinergic	2	0
Urticaria chronic	44	0
Urticaria contact	1	0
Urticaria papular	6	0
Urticaria thermal	11	0
Urticarial vasculitis	7	0
Skin disorders SOC TOTAL	**34481**	**2**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Social circumstances		
Age related issues		
Infant	2	0
Menarche	3	0
Menopause	52	0
Postmenopause	5	0
Criminal activity		
Verbal abuse	1	0
Dependents		
Sick relative	7	0
Dietary and nutritional issues		
Feeding tube user	1	0
Disability issues		
Bedridden	38	0
Breast prosthesis user	3	0
Disability	4	0
Hearing disability	4	0
Housebound	1	0
Immobile	13	0
Impaired driving ability	5	0
Impaired work ability	21	0
Loss of personal independence in daily activities	62	0
Mental disability	1	0
Physical disability	6	0
Sight disability	13	0
Sitting disability	4	0
Walking disability	3	0
Wheelchair user	1	0
Economic circumstances		
High income	1	0
Low income	1	0
Educational issues		
Educational problem	1	0
Illiteracy	2	0
Employment issues		
Job dissatisfaction	1	0
Retirement	4	0
Sick leave	1	0
Stress at work	3	0
Family and partner issues		
Bed sharing	1	0
Family stress	1	0
Non-occupational and unspecified environmental problems		
Flooding	2	0
Water pollution	2	0
Pregnancy related circumstances		
Breast feeding	17	0
Multigravida	1	0
Parity	1	0
Social issues NEC		
Exercise adequate	2	0
Hair dye user	2	0
Impaired quality of life	4	0
Patient dissatisfaction with treatment	1	0

Case Series Drug Analysis Print

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Report Run Date: 20-May-2022
Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968
MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Tobacco use		
Ex-tobacco user	1	0
Non-tobacco user	6	0
Tobacco user	1	0
Social circumstances SOC TOTAL	**306**	**0**

Case Series Drug Analysis Print

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Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
Adrenal gland therapeutic procedures		
Adrenalectomy	1	0
Anaesthesia and allied procedures		
Local anaesthesia	2	0
Nerve block	5	0
Analgesia supportive care		
Analgesic therapy	2	0
Antiinfective therapies		
COVID-19 prophylaxis	1	0
COVID-19 treatment	4	0
Arterial therapeutic procedures (excl aortic)		
Splenic artery embolisation	1	0
Blood and blood product treatment		
Transfusion	2	0
Breast therapeutic procedures NEC		
Axillary lymphadenectomy	3	0
Mammoplasty	1	0
Bronchial and pulmonary therapeutic procedures		
Airway secretion clearance therapy	1	0
Cardiac therapeutic procedures NEC		
Cardiac operation	1	0
Contraceptive methods female		
Contraception	1	0
Contraceptive implant	3	0
Oral contraception	1	0
Contraceptive methods male		
Condom	1	0
Dietary and nutritional therapies		
Medical diet	8	0
Nothing by mouth order	13	0
Wheat-free diet	1	0
External ear therapeutic procedures		
Ear irrigation	1	0
Facial therapeutic procedures		
Face lift	1	0
Fertility and fertilisation interventions female		
Endometrial scratching	1	0
Ovulation induction	2	0
Gastric therapeutic procedures		
Gastric operation	1	0
Gastrointestinal therapeutic procedures NEC		
Intestinal anastomosis	1	0
Prophylaxis of nausea and vomiting	16	0
Gynaecological therapeutic procedures NEC		
Menstrual cycle management	15	0
Haematological therapeutic procedures NEC		
Anticoagulant therapy	1	0
Head, neck and oral cavity therapeutic procedures NEC		
Neck lift	1	0
Hernia repairs		
Hernia repair	1	0
Hormonal therapeutic procedures NEC		
Hormone replacement therapy	2	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Surgical & medical procedures (Surgical & medical procedures cont'd)		
Hormone therapy	8	0
Immunisations		
COVID-19 immunisation	97	0
Immunisation	493	1
Vaccine coadministration	1	0
Induced abortions		
Abortion induced	1	0
Joint therapeutic procedures		
Joint injection	6	0
Joint surgery	1	0
Knee arthroplasty	1	0
Large intestine therapeutic procedures		
Appendicectomy	2	0
Limb therapeutic procedures		
Arm amputation	1	0
Limb immobilisation	12	0
Limb operation	10	0
Lymphoid tissue therapeutic procedures		
Lymphadenectomy	2	0
Splenectomy	1	0
Mastectomies		
Breast conserving surgery	5	0
Nail therapeutic procedures		
Nail operation	3	0
Nervous system therapeutic procedures NEC		
Multiple sclerosis relapse prophylaxis	3	0
Obstetric therapeutic procedures		
Caesarean section	1	0
Labour stimulation	1	0
Orbit and globe therapeutic procedures		
Strabismus correction	1	0
Ovarian therapeutic procedures		
Ovarian operation	1	0
Peripheral nerve therapeutic procedures		
Neurolysis	1	0
Peripheral nerve neurostimulation	1	0
Phototherapies		
UV light therapy	1	0
Prophylactic procedures NEC		
Anaphylaxis prophylaxis	3	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	1	0
Reproductive system disorder prophylaxis	1	0
Psychiatric therapies		
Electroconvulsive therapy	2	0
Renal therapeutic procedures		
Dialysis	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	4	0
Retinal therapeutic procedures		
Retinopexy	1	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	4	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Surgical & medical procedures (Surgical & medical procedures cont'd)		
Therapeutic skin care topical	1	0
Skull and brain therapeutic procedures		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0
Small intestine therapeutic procedures		
Ileostomy	1	0
Spine and spinal cord therapeutic procedures		
Spinal decompression	1	0
Tendon therapeutic procedures		
Tenodesis	1	0
Therapeutic bladder catheterisation		
Bladder catheterisation	2	0
Therapeutic procedures NEC		
Abscess drainage	1	0
Anaphylaxis treatment	7	0
Bed rest	6	0
Fatigue management	1	0
Hospitalisation	15	0
Injection	54	0
Interchange of vaccine products	335	0
Localised alternating hot and cold therapy	2	0
Magnetic therapy	1	0
Mass excision	5	0
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	2	0
Promotion of wound healing	1	0
Specialist consultation	1	0
Stent placement	1	0
Stoma care	1	0
Therapeutic procedure	2	0
Therapy change	2	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	2	0
Vascular therapeutic procedures NEC		
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	**1220**	**1**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Vascular disorders		
Accelerated and malignant hypertension		
Accelerated hypertension	1	0
Hypertensive crisis	16	0
Hypertensive urgency	2	0
Malignant hypertension	4	0
Aneurysms and dissections non-site specific		
Aneurysm	4	0
Aneurysm ruptured	1	0
Artery dissection	2	0
Aortic aneurysms and dissections		
Acute aortic syndrome	1	0
Aortic aneurysm	2	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
Aortic embolism and thrombosis		
Aortic embolus	5	0
Aortic thrombosis	4	0
Aortic infections and inflammations		
Aortitis	1	0
Aortic necrosis and vascular insufficiency		
Aortic occlusion	1	0
Aortic stenosis	2	0
Arterial infections and inflammations		
Arteritis	2	0
Giant cell arteritis	23	0
Blood pressure disorders NEC		
Blood pressure fluctuation	17	0
Labile blood pressure	5	0
Bruising, ecchymosis and purpura		
Achenbach syndrome	4	0
Circulatory collapse and shock		
CT hypotension complex	2	0
Circulatory collapse	93	0
Hypoperfusion	2	0
Hypovolaemic shock	2	1
Neurogenic shock	24	0
Peripheral circulatory failure	6	0
Shock	25	0
Shock symptom	4	0
Haemorrhages NEC		
Arterial haemorrhage	1	0
Bloody discharge	26	0
Haematoma	52	0
Haemorrhage	1415	2
Internal haemorrhage	14	1
Venous haemorrhage	2	0
Lymphangiopathies		
Lymphangiopathy	1	0
Lymphocele	7	0
Lymphorrhoea	2	0
Lymphostasis	1	0
Lymphoedemas		
Lymphoedema	251	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Non-site specific embolism and thrombosis		
Arterial thrombosis	5	0
Embolism	68	0
Embolism arterial	2	0
Embolism venous	8	1
Microembolism	2	0
Thrombosis	547	11
Venous thrombosis	8	0
Non-site specific necrosis and vascular insufficiency NEC		
Arterial occlusive disease	2	0
Arterial spasm	1	0
Arteriosclerosis	4	0
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	11	0
Peripheral venous disease	2	0
Vascular compression	1	0
Vascular occlusion	1	0
Vasospasm	1	0
Non-site specific vascular disorders NEC		
Capillary disorder	1	0
Capillary fragility	6	0
Endothelial dysfunction	1	0
Haemodynamic instability	1	0
Superficial vein prominence	3	0
Vascular fragility	1	0
Vascular pain	44	0
Vascular wall hypertrophy	1	0
Vasodilatation	46	0
Vein discolouration	7	0
Vein disorder	9	0
Vein rupture	7	0
Peripheral aneurysms and dissections		
Peripheral artery aneurysm	1	0
Peripheral embolism and thrombosis		
Axillary vein thrombosis	1	0
Blue toe syndrome	36	0
Deep vein thrombosis	370	1
Femoral artery embolism	1	0
Jugular vein thrombosis	5	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	4	0
Peripheral embolism	4	0
Subclavian artery thrombosis	1	0
Subclavian vein thrombosis	4	0
Superficial vein thrombosis	31	0
Thrombophlebitis	31	0
Peripheral vascular disorders NEC		
Cyanosis	58	0
Erythromelalgia	2	0
Flushing	484	0
Hot flush	1280	0
Peripheral vascular disorder	3	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022 Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Vein wall hypertrophy	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Claudication of jaw muscles	1	0
Extremity necrosis	3	0
Iliac artery occlusion	1	0
Intermittent claudication	3	0
Ischaemic limb pain	2	0
Jugular vein occlusion	2	0
May-Thurner syndrome	1	0
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	400	0
Peripheral ischaemia	13	0
Poor peripheral circulation	24	0
Raynaud's phenomenon	74	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
Phlebitis NEC		
Phlebitis	38	0
Phlebitis superficial	10	0
Site specific embolism and thrombosis NEC		
Brachiocephalic vein thrombosis	1	0
Site specific vascular disorders NEC		
Aortic disorder	1	0
Aortic rupture	2	2
Inferior vena cava dilatation	1	0
Pallor	451	0
Varicose veins NEC		
Spider vein	7	0
Varicophlebitis	4	0
Varicose vein	42	0
Varicose vein ruptured	1	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	6	0
Essential hypertension	6	0
Hypertension	797	0
Labile hypertension	2	0
Orthostatic hypertension	2	0
Secondary hypertension	1	0
Systolic hypertension	7	0
White coat hypertension	1	0
Vascular hypotensive disorders		
Capillary leak syndrome	1	0
Diastolic hypotension	1	0
Hypotension	475	1
Orthostatic hypotension	34	0
Vasculitides NEC		
Behcet's syndrome	5	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	3	0
MAGIC syndrome	2	0
Thromboangiitis obliterans	1	0
Vasculitis	58	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 20-May-2022
Data Lock Date: 18-May-2022 18:30:04
Earliest Reaction Date: 13-Apr-1968
MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Vena caval embolism and thrombosis		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	7637	21
TOTAL REACTIONS FOR DRUG	491839	773
TOTAL REPORTS	170867	
TOTAL FATAL OUTCOME REPORTS		773

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

Report Prepared by:

Worldwide Safety

Pfizer

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LIST OF ABBREVIATIONS

Acronym	Term
AE	adverse event
AESI	adverse event of special interest
BC	Brighton Collaboration
CDC	Centers for Disease Control and Prevention
COVID-19	coronavirus disease 2019
DLP	data lock point
EUA	emergency use authorisation
HLGT	(MedDRA) High Group Level Term
HLT	(MedDRA) High Level Term
MAH	marketing authorisation holder
MedDRA	medical dictionary for regulatory activities
MHRA	Medicines and Healthcare products Regulatory Agency
PCR	Polymerase Chain Reaction
PT	(MedDRA) Preferred Term
PVP	pharmacovigilance plan
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
RSI	reference safety information
TME	targeted medically event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SMQ	standardised MedDRA query
SOC	(MedDRA) System Organ Class
UK	United Kingdom
US	United States
VAED	vaccine-associated enhanced disease
VAERD	vaccine-associated enhanced respiratory disease
VAERS	vaccine adverse event reporting system

1. INTRODUCTION

Reference is made to the Request for Comments and Advice submitted 04 February 2021 regarding Pfizer/BioNTech's proposal for the clinical and post-authorization safety data package for the Biologics License Application (BLA) for our investigational COVID-19 Vaccine (BNT162b2). Further reference is made to the Agency's 09 March 2021 response to this request, and specifically, the following request from the Agency.

"Monthly safety reports primarily focus on events that occurred during the reporting interval and include information not relevant to a BLA submission such as line lists of adverse events by country. We are most interested in a cumulative analysis of post-authorization safety data to support your future BLA submission. Please submit an integrated analysis of your cumulative post-authorization safety data, including U.S. and foreign post-authorization experience, in your upcoming BLA submission. Please include a cumulative analysis of the Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in your Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). Please also include distribution data and an analysis of the most common adverse events. In addition, please submit your updated Pharmacovigilance Plan with your BLA submission."

This document provides an integrated analysis of the cumulative post-authorization safety data, including U.S. and foreign post-authorization adverse event reports received through 28 February 2021.

2. METHODOLOGY

Pfizer is responsible for the management post-authorization safety data on behalf of the MAH BioNTech according to the Pharmacovigilance Agreement in place. Data from BioNTech are included in the report when applicable.

Pfizer's safety database contains cases of AEs reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an AE, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.

- Because many external factors influence whether or not an AE is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these

proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.

- An accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

- Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity. The increased volume of reports has not impacted case processing for serious reports, and compliance metrics continue to be monitored weekly with prompt action taken as needed to maintain compliance with expedited reporting obligations. Non-serious cases are entered into the safety database no later than 4 calendar days from receipt. Entrance into the database includes the coding of all adverse events; this allow for a manual review of events being received but may not include immediate case processing to completion. Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately (b) (4) additional full-time employees (FTEs). More are joining each month with an expected total of more than (b) (4) additional resources by the end of June 2021.

3. RESULTS

3.1. Safety Database

3.1.1. General Overview

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

Table 1 below presents the main characteristics of the overall cases.

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17 18-30 31-50 51-64 65-74 ≥ 75 Unknown	175[a] 4953 13886 7884 3098 5214 6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in Figure 1, the System Organ Classes (SOCs) that contained the greatest number (≥2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness

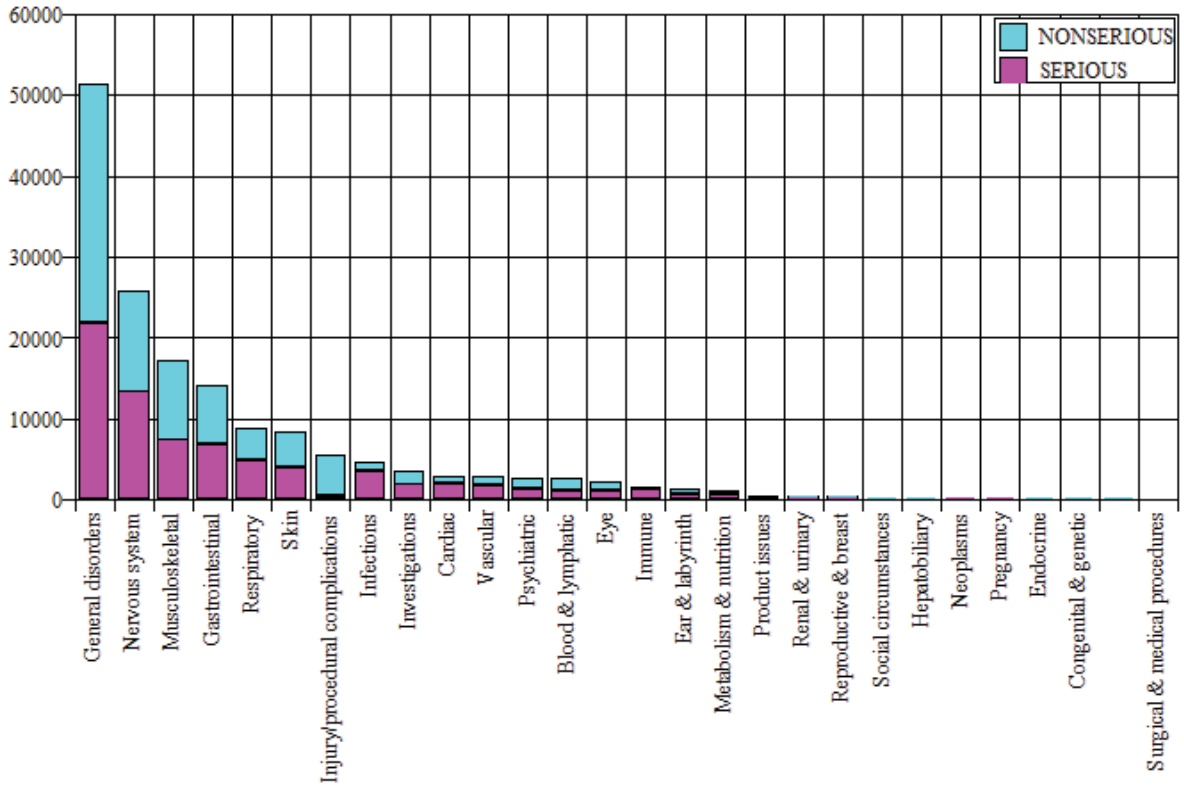

Table 2 shows the most commonly (≥2%) reported MedDRA (v. 23.1) PTs in the overall dataset (through 28 February 2021),

Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	**MedDRA PT**	**AEs (AERP%) N = 42086**
Blood and lymphatic system disorders		
	Lymphadenopathy	1972 (4.7%)
Cardiac disorders		
	Tachycardia	1098 (2.6%)
Gastrointestinal disorders		
	Nausea	5182 (12.3%)
	Diarrhoea	1880 (4.5%)
	Vomiting	1698 (4.0%)
General disorders and administration site conditions		
	Pyrexia	7666 (18.2%)
	Fatigue	7338 (17.4%)
	Chills	5514 (13.1%)
	Vaccination site pain	5181 (12.3%)

Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	**MedDRA PT**	**AEs (AERP%) N = 42086**
	Pain	3691 (8.8%)
	Malaise	2897 (6.9%)
	Asthenia	2285 (5.4%)
	Drug ineffective	2201 (5.2%)
	Vaccination site erythema	930 (2.2%)
	Vaccination site swelling	913 (2.2%)
	Influenza like illness	835 (2%)
Infections and infestations		
	COVID-19	1927 (4.6%)
Injury, poisoning and procedural complications		
	Off label use	880 (2.1%)
	Product use issue	828 (2.0%)
Musculoskeletal and connective tissue disorders		
	Myalgia	4915 (11.7%)
	Pain in extremity	3959 (9.4%)
	Arthralgia	3525 (8.4%)
Nervous system disorders		
	Headache	10131 (24.1%)
	Dizziness	3720 (8.8%)
	Paraesthesia	1500 (3.6%)
	Hypoaesthesia	999 (2.4%)
Respiratory, thoracic and mediastinal disorders		
	Dyspnoea	2057 (4.9%)
	Cough	1146 (2.7%)
	Oropharyngeal pain	948 (2.3%)
Skin and subcutaneous tissue disorders		
	Pruritus	1447 (3.4%)
	Rash	1404 (3.3%)
	Erythema	1044 (2.5%)
	Hyperhidrosis	900 (2.1%)
	Urticaria	862 (2.1%)
Total number of events		**93473**

3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan

Table 3. Safety concerns

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in Pregnancy and lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness

Table 4. Important Identified Risk

<table>
<tr><th>Topic</th><th>Description</th></tr>
<tr><td>Important Identified Risk</td><td>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)
Total Number of Cases in the Reporting Period (N=42086)</td></tr>
<tr><td>Anaphylaxis</td><td>Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 1833 potentially relevant cases were retrieved from the Anaphylactic reaction SMQ (Narrow and Broad) search strategy, applying the MedDRA algorithm. These cases were individually reviewed and assessed according to Brighton Collaboration (BC) definition and level of diagnostic certainty as shown in the Table below:

<table>
<tr><td>Brighton Collaboration Level</td><td>Number of cases</td></tr>
<tr><td>BC 1</td><td>290</td></tr>
<tr><td>BC 2</td><td>311</td></tr>
<tr><td>BC 3</td><td>10</td></tr>
<tr><td>BC 4</td><td>391</td></tr>
<tr><td>BC 5</td><td>831</td></tr>
<tr><td>Total</td><td>1833</td></tr>
</table>
Level 1 indicates a case with the highest level of diagnostic certainty of anaphylaxis, whereas the diagnostic certainty is lowest for Level 3. Level 4 is defined as “reported event of anaphylaxis with insufficient evidence to meet the case definition” and Level 5 as not a case of anaphylaxis.

There were 1002 cases (54.0% of the potentially relevant cases retrieved), 2958 potentially relevant events, from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy, meeting BC Level 1 to 4:

Country of incidence: UK (261), US (184), Mexico (99), Italy (82), Germany (67), Spain (38), France (36), Portugal (22), Denmark (20), Finland, Greece (19 each), Sweden (17), Czech Republic , Netherlands (16 each), Belgium, Ireland (13 each), Poland (12), Austria (11); the remaining 57 cases originated from 15 different countries.
Relevant event seriousness: Serious (2341), Non-Serious (617);
Gender: Females (876), Males (106), Unknown (20);
Age (n=961) ranged from 16 to 98 years (mean = 54.8 years, median = 42.5 years);
Relevant even outcome[a]: fatal (9)[b], resolved/resolving (1922), not resolved (229), resolved with sequelae (48), unknown (754);
Most frequently reported relevant PTs (≥2%), from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy: Anaphylactic reaction (435), Dyspnoea (356), Rash (190), Pruritus (175), Erythema (159), Urticaria (133), Cough (115), Respiratory distress, Throat tightness (97 each), Swollen tongue (93), Anaphylactic shock (80), Hypotension (72), Chest discomfort (71), Swelling face (70), Pharyngeal swelling (68), and Lip swelling (64).

Conclusion: Evaluation of BC cases Level 1 - 4 did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.</td></tr>
</table>

a Different clinical outcome may be reported for an event that occurred more than once to the same individual.
b There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their deaths

Table 5. Important Potential Risk

Topic	Description
Important Potential Risk	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)	No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue. The search criteria utilised to identify potential cases of VAED for this report includes PTs indicating a lack of effect of the vaccine and PTs potentially indicative of severe or atypical COVID-19[a]. Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 138 cases [0.33% of the total PM dataset], reporting 317 potentially relevant events were retrieved: Country of incidence: UK (71), US (25), Germany (14), France, Italy, Mexico, Spain, (4 each), Denmark (3); the remaining 9 cases originated from 9 different countries; Cases Seriousness: 138; Seriousness criteria for the total 138 cases: Medically significant (71, of which 8 also serious for disability), Hospitalization required (non-fatal/non-life threatening) (16, of which 1 also serious for disability), Life threatening (13, of which 7 were also serious for hospitalization), Death (38). Gender: Females (73), Males (57), Unknown (8); Age (n=132) ranged from 21 to 100 years (mean = 57.2 years, median = 59.5); Case outcome: fatal (38), resolved/resolving (26), not resolved (65), resolved with sequelae (1), unknown (8); Of the 317 relevant events, the most frequently reported PTs (≥2%) were: Drug ineffective (135), Dyspnoea (53), Diarrhoea (30), COVID-19 pneumonia (23), Vomiting (20), Respiratory failure (8), and Seizure (7). Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 75 cases could be definitively considered as VAED/VAERD. In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue.

a. Search criteria: Standard Decreased Therapeutic Response Search AND PTs Dyspnoea; Tachypnoea; Hypoxia; COVID 19 pneumonia; Respiratory Failure; Acute Respiratory Distress Syndrome; Cardiac Failure; Cardiogenic shock; Acute myocardial infarction; Arrhythmia; Myocarditis; Vomiting; Diarrhoea; Abdominal pain; Jaundice; Acute hepatic failure; Deep vein thrombosis; Pulmonary embolism; Peripheral Ischaemia; Vasculitis; Shock; Acute kidney injury; Renal failure; Altered state of consciousness; Seizure; Encephalopathy; Meningitis; Cerebrovascular accident; Thrombocytopenia; Disseminated intravascular coagulation; Chillblains; Erythema multiforme; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children.

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Use in Pregnancy and lactation	• Number of cases: 413[a] (0.98% of the total PM dataset); 84 serious and 329 non-serious; • Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each), Romania (4), Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries. Pregnancy cases: 274 cases including: • 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins). • Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted). • 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2). • 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Abortion spontaneous (25), Uterine contraction during pregnancy, Premature rupture of membranes, Abortion, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases). • 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester. Breast feeding baby cases: 133, of which: • 116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events; • 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant/child exposed to vaccine via breastfeeding: Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each). Breast feeding mother cases (6): • 1 serious case reported 3 clinical events that occurred in a mother during breast feeding (PT Maternal exposure during breast feeding); these events coded to the PTs Chills, Malaise, and Pyrexia • 1 non-serious case reported with very limited information and without associated AEs.

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
	• In 4 cases (3 non-serious; 1 serious) Suppressed lactation occurred in a breast feeding women with the following co-reported events: Pyrexia (2), Paresis, Headache, Chills, Vomiting, Pain in extremity, Arthralgia, Breast pain, Scar pain, Nausea, Migraine, Myalgia, Fatigue and Breast milk discolouration (1 each). Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding.
Use in Paediatric Individuals <12 Years of Age	<u>Paediatric individuals <12 years of age</u> • Number of cases: 34[d] (0.1% of the total PM dataset), indicative of administration in paediatric subjects <12 years of age; • Country of incidence: UK (29), US (3), Germany and Andorra (1 each); • Cases Seriousness: Serious (24), Non-Serious (10); • Gender: Females (25), Males (7), Unknown (2); • Age (n=34) ranged from 2 months to 9 years, mean = 3.7 years, median = 4.0; • Case outcome: resolved/resolving (16), not resolved (13), and unknown (5). • Of the 132 reported events, those reported more than once were as follows: Product administered to patient of inappropriate age (27, see Medication Error), Off label use (11), Pyrexia (6), Product use issue (5), Fatigue, Headache and Nausea (4 each), Vaccination site pain (3), Abdominal pain upper, COVID-19, Facial paralysis, Lymphadenopathy, Malaise, Pruritus and Swelling (2 each). Conclusion: No new significant safety information was identified based on a review of these cases compared with the non-paediatric population.
Vaccine Effectiveness	Company conventions for coding cases indicative of lack of efficacy: The coding conventions for lack of efficacy in the context of administration of the COVID-19 vaccine were revised on 15 February 2021, as shown below: • PT "Vaccination failure" is coded when ALL of the following criteria are met: o The subject has received the series of two doses per the dosing regimen in local labeling. o At least 7 days have elapsed since the second dose of vaccine has been administered. o The subject experiences SARS-CoV-2 infection (confirmed laboratory tests). • PT "Drug ineffective" is coded when either of the following applies: o The infection is not confirmed as SARS-CoV-2 through laboratory tests (irrespective of the vaccination schedule). This includes scenarios where LOE is stated or implied, e.g., "the vaccine did not work", "I got COVID-19". o It is unknown: ▪ Whether the subject has received the series of two doses per the dosing regimen in local labeling; ▪ How many days have passed since the first dose (including unspecified number of days like" a few days", "some days", etc.); ▪ If 7 days have passed since the second dose; o The subject experiences a vaccine preventable illness 14 days after receiving the first dose up to and through 6 days after receipt of the second dose. Note: after the immune system as had sufficient time (14 days) to respond to the vaccine, a report of COVID-19 is considered a potential lack of efficacy even if the vaccination course is not complete. Summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date:

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**

1st dose (day 1-13)	From day 14 post 1st dose to day 6 post 2nd dose	Day 7 post 2nd dose
Code only the events describing the SARS-CoV-2 infection	Code "Drug ineffective"	Code "Vaccination failure"
Scenario Not considered LOE	Scenario considered LOE as "Drug ineffective"	Scenario considered LOE as "Vaccination failure"

Lack of efficacy cases

- Number of cases: 1665[b] (3.9 % of the total PM dataset) of which 1100 were medically confirmed and 565 non medically confirmed;
- Number of lack of efficacy events: 1665 [PT: Drug ineffective (1646) and Vaccination failure (19)[f]].
- Country of incidence: US (665), UK (405), Germany (181), France (85), Italy (58), Romania (47), Belgium (33), Israel (30), Poland (28), Spain (21), Austria (18), Portugal (17), Greece (15), Mexico (13), Denmark (8), Canada (7), Hungary, Sweden and United Arab Emirates (5 each), Czech Republic (4), Switzerland (3); the remaining 12 cases originated from 9 different countries.
- COVID-19 infection was suspected in 155 cases, confirmed in 228 cases, in 1 case it was reported that the first dose was not effective (no other information).
- COVID-19 infection (suspected or confirmed) outcome was reported as resolved/resolving (165), not resolved (205) or unknown (1230) at the time of the reporting; there were 65 cases where a fatal outcome was reported.

Drug ineffective cases (1649)

- Drug ineffective event seriousness: serious (1625), non-serious (21)[e];
- Lack of efficacy term was reported:
  - after the 1st dose in 788 cases
  - after the 2nd dose in 139 cases
  - in 722 cases it was unknown after which dose the lack of efficacy occurred.
- Latency of lack of efficacy term reported after the first dose was known for 176 cases:
  - Within 9 days: 2 subjects;
  - Within 14 and 21 days: 154 subjects;
  - Within 22 and 50 days: 20 subjects;
- Latency of lack of efficacy term reported after the second dose was known for 69 cases:
  - Within 0 and 7 days: 42 subjects;
  - Within 8 and 21 days: 22 subjects;
  - Within 23 and 36 days: 5 subjects.
- Latency of lack of efficacy term reported in cases where the number of doses administered was not provided, was known in 409 cases:
  - Within 0 and 7 days after vaccination: 281 subjects.
  - Within 8 and 14 days after vaccination: 89 subjects.
  - Within 15 and 44 days after vaccination: 39 subjects.

According to the RSI, individuals may not be fully protected until 7 days after their second dose of vaccine, therefore for the above 1649 cases where lack of efficacy was reported after the 1st dose or the

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
	2nd dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness. ***Vaccination failure cases (16)*** • Vaccination failure seriousness: all serious; • Lack of efficacy term was reported in all cases after the 2nd dose: • Latency of lack of efficacy was known for 14 cases: o Within 7 and 13 days: 8 subjects; o Within 15 and 29 days: 6 subjects. COVID-19 (10) and Asymptomatic COVID-19 (6) were the reported vaccine preventable infections that occurred in these 16 cases. Conclusion: No new safety signals of vaccine lack of efficacy have emerged based on a review of these cases.

a. From a total of 417 cases, 4 cases were excluded from the analysis. In 3 cases, the MAH was informed that a 33-year-old and two unspecified age pregnant female patients were scheduled to receive bnt162b2 (PT reported Off label use and Product use issue in 2 cases; Circumstance or information capable of leading to medication error in one case). One case reported the PT Morning sickness; however, pregnancy was not confirmed in this case.
b. 558 additional cases retrieved in this dataset were excluded from the analysis; upon review, 546 cases cannot be considered true lack of efficacy cases because the PT Drug ineffective was coded but the subjects developed SARS-CoV-2 infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; in 5 cases the PT Drug ineffective was removed after data lock point (DLP) because the subjects did not develop COVID-19 infection; in 1 case, reporting Treatment failure and Transient ischaemic attack, the Lack of efficacy PT did not refer to BNT162b2 vaccine; 5 cases have been invalidated in the safety database after DLP; 1 case has been deleted from the discussion because the PTs reported Pathogen resistance and Product preparation issue were not indicative of a lack of efficacy. to be eliminated.
c. Upon review, 31 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects
d. Upon review, 28 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects.
e. Different clinical outcomes may be reported for an event that occurred more than once to the same individual
f. In 2 cases the PT Vaccination failure was replaced with Drug ineffective after DLP. Another case was not included in the discussion of the Vaccination failure cases because correct scheduling (21 days apart between the first and second dose) cannot be confirmed.

3.1.3. Review of Adverse Events of Special Interest (AESIs)

Please refer to Appendix 1 for the list of the company's AESIs for BNT162b2.

The company's AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).

The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general.

The AESI list is comprised of MedDRA PTs, HLTs, HLGTs or MedDRA SMQs and can be changed as appropriate based on the evolving safety profile of the vaccine.

Table 7 provides a summary review of cumulative cases within AESI categories in the Pfizer safety database. This is distinct from safety signal evaluations which are conducted and included, as appropriate, in the Summary Monthly Safety Reports submitted regularly to the FDA and other Health Authorities.

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
Anaphylactic Reactions *Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria*	Please refer to the Risk 'Anaphylaxis' included above in Table 4.
Cardiovascular AESIs *Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia*	• Number of cases: 1403 (3.3% of the total PM dataset), of which 241 are medically confirmed and 1162 are non-medically confirmed; • Country of incidence: UK (268), US (233), Mexico (196), Italy (141), France (128), Germany (102), Spain (46), Greece (45), Portugal (37), Sweden (20), Ireland (17), Poland (16), Israel (13), Austria, Romania and Finland (12 each), Netherlands (11), Belgium and Norway (10 each), Czech Republic (9), Hungary and Canada (8 each), Croatia and Denmark (7 each), Iceland (5); the remaining 30 cases were distributed among 13 other countries; • Subjects' gender: female (1076), male (291) and unknown (36); • Subjects' age group (n = 1346): Adult[c] (1078), Elderly[d] (266) Child[e] and Adolescent[f] (1 each); • Number of relevant events: 1441, of which 946 serious, 495 non-serious; in the cases reporting relevant serious events; • Reported relevant PTs: Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6); • Relevant event onset latency (n = 1209): Range from <24 hours to 21 days, median <24 hours;

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Relevant event outcome[g]: fatal (136), resolved/resolving (767), resolved with sequelae (21), not resolved (140) and unknown (380); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
COVID-19 AESIs *Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmia*	• Number of cases: 3067 (7.3% of the total PM dataset), of which 1013 are medically confirmed and 2054 are non-medically confirmed; • Country of incidence: US (1272), UK (609), Germany (360), France (161), Italy (94), Spain (69), Romania (62), Portugal (51), Poland (50), Mexico (43), Belgium (42), Israel (41), Sweden (30), Austria (27), Greece (24), Denmark (18), Czech Republic and Hungary (17 each), Canada (12), Ireland (11), Slovakia (9), Latvia and United Arab Emirates (6 each); the remaining 36 cases were distributed among 16 other different countries; • Subjects' gender: female (1650), male (844) and unknown (573); • Subjects' age group (n= 1880): Adult (1315), Elderly (560), Infant[h] and Adolescent (2 each), Child (1); • Number of relevant events: 3359, of which 2585 serious, 774 non-serious; • Most frequently reported relevant PTs (>1 occurrence): COVID-19 (1927), SARS-CoV-2 test positive (415), Suspected COVID-19 (270), Ageusia (228), Anosmia (194), SARS-CoV-2 antibody test negative (83), Exposure to SARS-CoV-2 (62), SARS-CoV-2 antibody test positive (53), COVID-19 pneumonia (51), Asymptomatic COVID-19 (31), Coronavirus infection (13), Occupational exposure to SARS-CoV-2 (11), SARS-CoV-2 test false positive (7), Coronavirus test positive (6), SARS-CoV-2 test negative (3) SARS-CoV-2 antibody test (2); • Relevant event onset latency (n = 2070): Range from <24 hours to 374 days, median 5 days; • Relevant event outcome: fatal (136), not resolved (547), resolved/resolving (558), resolved with sequelae (9) and unknown (2110). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Dermatological AESIs *Search criteria: PT Chillblains; Erythema multiforme*	• Number of cases: 20 cases (0.05% of the total PM dataset), of which 15 are medically confirmed and 5 are non-medically confirmed; • Country of incidence: UK (8), France and Poland (2 each), and the remaining 8 cases were distributed among 8 other different countries; • Subjects' gender: female (17) male and unknown (1 each); • Subjects' age group (n=19): Adult (18), Elderly (1); • Number of relevant events: 20 events, 16 serious, 4 non-serious

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Reported relevant PTs: Erythema multiforme (13) and Chillblains (7) • Relevant event onset latency (n = 18): Range from <24 hours to 17 days, median 3 days; • Relevant event outcome: resolved/resolving (7), not resolved (8) and unknown (6). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Haematological AESIs *Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Immune thrombocytopenia, Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms*	• Number of cases: 932 (2.2 % of the total PM dataset), of which 524 medically confirmed and 408 non-medically confirmed; • Country of incidence: UK (343), US (308), France (50), Germany (43), Italy (37), Spain (27), Mexico and Poland (13 each), Sweden (10), Israel (9), Netherlands (8), Denmark, Finland, Portugal and Ireland (7 each), Austria and Norway (6 each), Croatia (4), Greece, Belgium, Hungary and Switzerland (3 each), Cyprus, Latvia and Serbia (2 each); the remaining 9 cases originated from 9 different countries; • Subjects' gender (n=898): female (676) and male (222); • Subjects' age group (n=837): Adult (543), Elderly (293), Infant (1); • Number of relevant events: 1080, of which 681 serious, 399 non-serious; • Most frequently reported relevant PTs (≥15 occurrences) include: Epistaxis (127), Contusion (112), Vaccination site bruising (96), Vaccination site haemorrhage (51), Petechiae (50), Haemorrhage (42), Haematochezia (34), Thrombocytopenia (33), Vaccination site haematoma (32), Conjunctival haemorrhage and Vaginal haemorrhage (29 each), Haematoma, Haemoptysis and Menorrhagia (27 each), Haematemesis (25), Eye haemorrhage (23), Rectal haemorrhage (22), Immune thrombocytopenia (20), Blood urine present (19), Haematuria, Neutropenia and Purpura (16 each) Diarrhoea haemorrhagic (15); • Relevant event onset latency (n = 787): Range from <24 hours to 33 days, median = 1 day; • Relevant event outcome: fatal (34), resolved/resolving (393), resolved with sequelae (17), not resolved (267) and unknown (371). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Hepatic AESIs *Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury*	• Number of cases: 70 cases (0.2% of the total PM dataset), of which 54 medically confirmed and 16 non-medically confirmed; • Country of incidence: UK (19), US (14), France (7), Italy (5), Germany (4), Belgium, Mexico and Spain (3 each), Austria, and Iceland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (43), male (26) and unknown (1); • Subjects' age group (n=64): Adult (37), Elderly (27);

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Number of relevant events: 94, of which 53 serious, 41 non-serious; • Most frequently reported relevant PTs (≥3 occurrences) include: Alanine aminotransferase increased (16), Transaminases increased and Hepatic pain (9 each), Liver function test increased (8), Aspartate aminotransferase increased and Liver function test abnormal (7 each), Gamma-glutamyltransferase increased and Hepatic enzyme increased (6 each), Blood alkaline phosphatase increased and Liver injury (5 each), Ascites, Blood bilirubin increased and Hypertransaminasaemia (3 each); • Relevant event onset latency (n = 57): Range from <24 hours to 20 days, median 3 days; • Relevant event outcome: fatal (5), resolved/resolving (27), resolved with sequelae (1), not resolved (14) and unknown (47). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Facial Paralysis *Search criteria: PTs Facial paralysis, Facial paresis*	• Number of cases: 449[i] (1.07% of the total PM dataset), 314 medically confirmed and 135 non-medically confirmed; • Country of incidence: US (124), UK (119), Italy (40), France (27), Israel (20), Spain (18), Germany (13), Sweden (11), Ireland (9), Cyprus (8), Austria (7), Finland and Portugal (6 each), Hungary and Romania (5 each), Croatia and Mexico (4 each), Canada (3),Czech Republic, Malta, Netherlands, Norway, Poland and Puerto Rico (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (295), male (133), unknown (21); • Subjects' age group (n=411): Adult (313), Elderly (96), Infant[j] and Child (1 each); • Number of relevant events[k]: 453, of which 399 serious, 54 non-serious; • Reported relevant PTs: Facial paralysis (401), Facial paresis (64); • Relevant event onset latency (n = 404): Range from <24 hours to 46 days, median 2 days; • Relevant event outcome: resolved/resolving (184), resolved with sequelae (3), not resolved (183) and unknown (97); Overall Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. Causality assessment will be further evaluated following availability of additional unblinded data from the clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non-interventional post-authorisation safety studies, C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell's palsy in vaccinated individuals. The timeline for conducting these analyses will be established based on the size of the vaccinated population captured in the study data sources by the first interim reports (due 30 June

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk.
Immune-Mediated/Autoimmune AESIs *Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity*	• Number of cases: 1050 (2.5 % of the total PM dataset), of which 760 medically confirmed and 290 non-medically confirmed; • Country of incidence (>10 cases): UK (267), US (257), Italy (70), France and Germany (69 each), Mexico (36), Sweden (35), Spain (32), Greece (31), Israel (21), Denmark (18), Portugal (17), Austria and Czech Republic (16 each), Canada (12), Finland (10). The remaining 74 cases were from 24 different countries. • Subjects' gender (n=682): female (526), male (156). • Subjects' age group (n=944): Adult (746), Elderly (196), Adolescent (2). • Number of relevant events: 1077, of which 780 serious, 297 non-serious. • Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (596), Neuropathy peripheral (49), Pericarditis (32), Myocarditis (25), Dermatitis (24), Diabetes mellitus and Encephalitis (16 each), Psoriasis (14), Dermatitis Bullous (13), Autoimmune disorder and Raynaud's phenomenon (11 each); • Relevant event onset latency (n = 807): Range from <24 hours to 30 days, median <24 hours. • Relevant event outcome[l]: resolved/resolving (517), not resolved (215), fatal (12), resolved with sequelae (22) and unknown (312). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Musculoskeletal AESIs *Search criteria: PTs Arthralgia; Arthritis; Arthritis bacterial[n]; Chronic fatigue syndrome; Polyarthritis; Polyneuropathy; Post viral fatigue syndrome; Rheumatoid arthritis*	• Number of cases: 3600 (8.5% of the total PM dataset), of which 2045 medically confirmed and 1555 non-medically confirmed; • Country of incidence: UK (1406), US (1004), Italy (285), Mexico (236), Germany (72), Portugal (70), France (48), Greece and Poland (46), Latvia (33), Czech Republic (32), Israel and Spain (26), Sweden (25), Romania (24), Denmark (23), Finland and Ireland (19 each), Austria and Belgium (18 each), Canada (16), Netherlands (14), Bulgaria (12), Croatia and Serbia (9 each), Cyprus and Hungary (8 each), Norway (7), Estonia and Puerto Rico (6 each), Iceland and Lithuania (4 each); the remaining 21 cases originated from 11 different countries; • Subjects' gender (n=3471): female (2760), male (711); • Subjects' age group (n=3372): Adult (2850), Elderly (515), Child (4), Adolescent (2), Infant (1); • Number of relevant events: 3640, of which 1614 serious, 2026 non-serious; • Reported relevant PTs: Arthralgia (3525), Arthritis (70), Rheumatoid arthritis (26), Polyarthritis (5), Polyneuropathy, Post viral fatigue syndrome, Chronic fatigue syndrome (4 each), Arthritis bacterial (1); • Relevant event onset latency (n = 2968): Range from <24 hours to 32 days, median 1 day;

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Relevant event outcome: resolved/resolving (1801), not resolved (959), resolved with sequelae (49), and unknown (853). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Neurological AESIs (including demyelination) *Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Narcolepsy*	• Number of cases: 501 (1.2% of the total PM dataset), of which 365 medically confirmed and 136 non-medically confirmed. • Country of incidence (≥9 cases): UK (157), US (68), Germany (49), Mexico (35), Italy (31), France (25), Spain (18), Poland (17), Netherlands and Israel (15 each), Sweden (9). The remaining 71 cases were from 22 different countries. • Subjects' gender (n=478): female (328), male (150). • Subjects' age group (n=478): Adult (329), Elderly (149); • Number of relevant events: 542, of which 515 serious, 27 non-serious. • Most frequently reported relevant PTs (>2 occurrences) included: Seizure (204), Epilepsy (83), Generalised tonic-clonic seizure (33), Guillain-Barre syndrome (24), Fibromyalgia and Trigeminal neuralgia (17 each), Febrile convulsion, (15), Status epilepticus (12), Aura and Myelitis transverse (11 each), Multiple sclerosis relapse and Optic neuritis (10 each), Petit mal epilepsy and Tonic convulsion (9 each), Ataxia (8), Encephalopathy and Tonic clonic movements (7 each), Foaming at mouth (5), Multiple sclerosis, Narcolepsy and Partial seizures (4 each), Bad sensation, Demyelination, Meningitis, Postictal state, Seizure like phenomena and Tongue biting (3 each); • Relevant event onset latency (n = 423): Range from <24 hours to 48 days, median 1 day; • Relevant events outcome: fatal (16), resolved/resolving (265), resolved with sequelae (13), not resolved (89) and unknown (161); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Other AESIs *Search criteria: Herpes viral infections (HLT) (Primary Path) OR PTs Adverse event following immunisation; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Middle East respiratory syndrome; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient*	• Number of cases: 8152 (19.4% of the total PM dataset), of which 4977 were medically confirmed and 3175 non-medically confirmed; • Country of incidence (> 20 occurrences): UK (2715), US (2421), Italy (710), Mexico (223), Portugal (210), Germany (207), France (186), Spain (183), Sweden (133), Denmark (127), Poland (120), Greece (95), Israel (79), Czech Republic (76), Romania (57), Hungary (53), Finland (52), Norway (51), Latvia (49), Austria (47), Croatia (42), Belgium (41), Canada (39), Ireland (34), Serbia (28), Iceland (25), Netherlands (22). The remaining 127 cases were from 21 different countries; • Subjects' gender (n=7829): female (5969), male (1860); • Subjects' age group (n=7479): Adult (6330), Elderly (1125), Adolescent, Child (9 each), Infant (6);

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive	• Number of relevant events: 8241, of which 3674 serious, 4568 non-serious; • Most frequently reported relevant PTs (≥6 occurrences) included: Pyrexia (7666), Herpes zoster (259), Inflammation (132), Oral herpes (80), Multiple organ dysfunction syndrome (18), Herpes virus infection (17), Herpes simplex (13), Ophthalmic herpes zoster (10), Herpes ophthalmic and Herpes zoster reactivation (6 each); • Relevant event onset latency (n =6836): Range from <24 hours to 61 days, median 1 day; • Relevant events outcome: fatal (96), resolved/resolving (5008), resolved with sequelae (84), not resolved (1429) and unknown (1685). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Pregnancy Related AESIs *Search criteria: PTs Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia*	For relevant cases, please refer to Table 6, Description of Missing Information, *Use in Pregnancy and While Breast Feeding*
Renal AESIs *Search criteria: PTs Acute kidney injury; Renal failure.*	• Number of cases: 69 cases (0.17% of the total PM dataset), of which 57 medically confirmed, 12 non-medically confirmed; • Country of incidence: Germany (17), France and UK (13 each), US (6), Belgium, Italy and Spain (4 each), Sweden (2), Austria, Canada, Denmark, Finland, Luxembourg and Norway (1 each); • Subjects' gender: female (46), male (23); • Subjects' age group (n=68): Adult (7), Elderly (60), Infant (1); • Number of relevant events: 70, all serious; • Reported relevant PTs: Acute kidney injury (40) and Renal failure (30); • Relevant event onset latency (n = 42): Range from <24 hours to 15 days, median 4 days; • Relevant event outcome: fatal (23), resolved/resolving (10), not resolved (15) and unknown (22). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Respiratory AESIs *Search criteria: Lower respiratory tract infections NEC (HLT)*	• Number of cases: 130 cases (0.3% of the total PM dataset), of which 107 medically confirmed;

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
(Primary Path) OR Respiratory failures (excl neonatal) (HLT) (Primary Path) OR Viral lower respiratory tract infections (HLT) (Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome	• Countries of incidence: United Kingdom (20), France (18), United States (16), Germany (14), Spain (13), Belgium and Italy (9), Denmark (8), Norway (5), Czech Republic, Iceland (3 each); the remaining 12 cases originated from 8 different countries. • Subjects' gender (n=130): female (72), male (58). • Subjects's age group (n=126): Elderly (78), Adult (47), Adolescent (1). • Number of relevant events: 137, of which 126 serious, 11 non-serious; • Reported relevant PTs: Respiratory failure (44), Hypoxia (42), Respiratory disorder (36), Acute respiratory distress syndrome (10), Chronic respiratory syndrome (3), Severe acute respiratory syndrome (2). • Relevant event onset latency (n=102): range from < 24 hours to 18 days, median 1 day; • Relevant events outcome: fatal (41), Resolved/resolving (47), not recovered (18) and unknown (31). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Thromboembolic Events *Search criteria: Embolism and thrombosis (HLGT) (Primary Path), excluding PTs reviewed as Stroke AESIs, OR PTs Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism*	• Number of cases: 151 (0.3% of the total PM dataset), of which 111 medically confirmed and 40 non-medically confirmed; • Country of incidence: UK (34), US (31), France (20), Germany (15), Italy and Spain (6 each), Denmark and Sweden (5 each), Austria, Belgium and Israel (3 each), Canada, Cyprus, Netherlands and Portugal (2 each); the remaining 12 cases originated from 12 different countries; • Subjects' gender (n= 144): female (89), male (55); • Subjects' age group (n=136): Adult (66), Elderly (70); • Number of relevant events: 168, of which 165 serious, 3 non-serious; • Most frequently reported relevant PTs (>1 occurrence) included: Pulmonary embolism (60), Thrombosis (39), Deep vein thrombosis (35), Thrombophlebitis superficial (6), Venous thrombosis limb (4), Embolism, Microembolism, Thrombophlebitis and Venous thrombosis (3 each) Blue toe syndrome (2); • Relevant event onset latency (n = 124): Range from <24 hours to 28 days, median 4 days; • Relevant event outcome: fatal (18), resolved/resolving (54), resolved with sequelae (6), not resolved (49) and unknown (42). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Stroke *Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents*	• Number of cases: 275 (0.6% of the total PM dataset), of which 180 medically confirmed and 95 non-medically confirmed; • Country of incidence: UK (81), US (66), France (32), Germany (21), Norway (14), Netherlands and Spain (11 each), Sweden (9),

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
(Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)	Israel (6), Italy (5), Belgium (3), Denmark, Finland, Poland and Switzerland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender (n= 273): female (182), male (91); • Subjects' age group (n=265): Adult (59), Elderly (205), Child[m] (1); • Number of relevant events: 300, all serious; • Most frequently reported relevant PTs (>1 occurrence) included: o PTs indicative of Ischaemic stroke: Cerebrovascular accident (160), Ischaemic stroke (41), Cerebral infarction (15), Cerebral ischaemia, Cerebral thrombosis, Cerebral venous sinus thrombosis, Ischaemic cerebral infarction and Lacunal infarction (3 each) Basal ganglia stroke, Cerebellar infarction and Thrombotic stroke (2 each); o PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage (26), Haemorrhagic stroke (11), Haemorrhage intracranical and Subarachnoid haemorrhage (5 each), Cerebral haematoma (4), Basal ganglia haemorrhage and Cerebellar haemorrhage (2 each); • Relevant event onset latency (n = 241): Range from <24 hours to 41 days, median 2 days; • Relevant event outcome: fatal and resolved/resolving (61 each), resolved with sequelae (10), not resolved (85) and unknown (83). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Vasculitic Events *Search criteria: Vasculitides HLT*	• Number of cases: 32 cases (0.08% of the total PM dataset), of which 26 medically confirmed and 6 non-medically confirmed; • Country of incidence: UK (13), France (4), Portugal, US and Spain (3 each), Cyprus, Germany, Hungary, Italy and Slovakia and Costa rica (1 each); • Subjects' gender: female (26), male (6); • Subjects' age group (n=31): Adult (15), Elderly (16); • Number of relevant events: 34, of which 25 serious, 9 non-serious; • Reported relevant PTs: Vasculitis (14), Cutaneous vasculitis and Vasculitic rash (4 each), (3), Giant cell arteritis and Peripheral ischaemia (3 each), Behcet's syndrome and Hypersensitivity vasculitis (2 each) Palpable purpura, and Takayasu's arteritis (1 each); • Relevant event onset latency (n = 25): Range from <24 hours to 19 days, median 3 days; • Relevant event outcome: fatal (1), resolved/resolving (13), not resolved (12) and unknown (8). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)

a. For the complete list of the AESIs, please refer to Appendix 5;
b. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
c. Subjects with age ranged between 18 and 64 years;
d. Subjects with age equal to or above 65 years;
e. Subjects with age ranged between 2 and 11 years;
f. Subjects with age ranged between 12 and less than 18 years;
g. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events;
h. Subjects with age ranged between 1 (28 days) and 23 months;
i. Twenty-four additional cases were excluded from the analysis as they were not cases of peripheral facial nerve palsy because they described other disorders (stroke, cerebral haemorrhage or transient ischaemic attack); 1 case was excluded from the analysis because it was invalid due to an unidentifiable reporter;
j. This UK case report received from the UK MHRA described a 1-year-old subject who received the vaccine, and had left postauricular ear pain that progressed to left-sided Bell's palsy 1 day following vaccination that had not resolved at the time of the report;
k. If a case included both PT Facial paresis and PT Facial paralysis, only the PT Facial paralysis was considered in the descriptions of the events as it is most clinically important;
l. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events
m. This UK case report received from the UK MHRA described a 7-year-old female subject who received the vaccine and had stroke (unknown outcome); no follow-up is possible for clarification.
n. This PT not included in the AESIs/TME list was included in the review as relevant for ACCESS protocol criteria;

3.1.4. Medication error

Cases potentially indicative of medication errors[1] that cumulatively occurred are summarized below.

- Number of relevant medication error cases: 2056[2] (4.9%) of which 1569 (3.7%) are medically confirmed.
- Number of relevant events: 2792
- Top 10 countries of incidence:
  - US (1201), France (171), UK (138), Germany (88), Czech Republic (87), Sweden (49), Israel (45), Italy (42), Canada (35), Romania (33), Finland (21), Portugal (20), Norway (14), Puerto Rico (13), Poland (12), Austria and Spain (10 each).

  Medication error case outcomes:

  - Fatal (7)[3],
  - Recovered/recovering (354, of which 4 are serious),
  - Recovered with sequelae (8, of which 3 serious)

[1] MedDRA (version 23.1) Higher Level Terms: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.

[2] Thirty-five (35) cases were exclude from the analysis because describing medication errors occurring in an unspecified number of individuals or describing medication errors occurring with co suspects were determined to be non-contributory.

[3] All the medication errors reported in these cases were assessed as non-serious occurrences with an unknown outcome; based on the available information including the causes of death, the relationship between the medication error and the death is weak. .

- Not recovered (189, of which 84 are serious),
- Unknown (1498, of which 33 are serious).

1371 cases reported only MEs without any associated clinical adverse event. The PTs most frequently reported (≥12 occurrences) were: Poor quality product administered (539), Product temperature excursion issue (253), Inappropriate schedule of product administration (225), Product preparation error (206), Underdose (202), Circumstance or information capable of leading to medication error (120), Product preparation issue (119), Wrong technique in product usage process (76), Incorrect route of product administration (66), Accidental overdose (33), Product administered at inappropriate site (27), Incorrect dose administered and Accidental exposure to the product (25 each), Exposure via skin contact (22), Wrong product administered (17), Incomplete course of vaccination, and Product administration error (14 each) Product administered to patient of inappropriate age (12).

In 685 cases, there were co-reported AEs. The most frequently co- associated AEs (> 40 occurrences) were: Headache (187), Pyrexia (161), Fatigue (135), Chills (127), Pain (107), Vaccination site pain (100), Nausea (89), Myalgia (88), Pain in extremity (85) Arthralgia (68), Off label use (57), Dizziness (52), Lymphadenopathy (47), Asthenia (46) and Malaise (41). These cases are summarized in Table 8.

Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Accidental exposure to product	0	0	0	5
Accidental overdose	4	1	9	6
Booster dose missed	0	0	0	1
Circumstance or information capable of leading to medication error	0	0	5	11
Contraindicated product administered	1	0	0	2
Expired product administered	0	0	0	2
Exposure via skin contact	0	0	0	5
Inappropriate schedule of product administration	0	2	8	264
Incorrect dose administered	1	1	0	0

Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Incorrect route of product administration	2	6	16	127
Lack of vaccination site rotation	1	0	0	0
Medication error	0	0	0	1
Poor quality product administered	1	0	0	34
Product administered at inappropriate site	2	1	13	29
Product administered to patient of inappropriate age	0	4	0	40
Product administration error	1	0	0	3
Product dose omission issue	0	1	0	3
Product preparation error	1	0	4	11
Product preparation issue	1	1	0	14

Overall, there were 68 cases with co-reported AEs reporting Harm and 599 cases with co-reported AEs without harm. Additionally, Intercepted medication errors was reported in 1 case (PTs Malaise, clinical outcome unknow) and Potential medication errors were reported in 17 cases.

4. DISCUSSION

Pfizer performs frequent and rigorous signal detection on BNT162b2 cases. The findings of these signal detection analyses are consistent with the known safety profile of the vaccine. This cumulative analysis to support the Biologics License Application for BNT162b2, is an integrated analysis of post-authorization safety data, from U.S. and foreign experience, focused on Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in the Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine.

5. SUMMARY AND CONCLUSION

Review of the available data for this cumulative PM experience, confirms a favorable benefit: risk balance for BNT162b2.

Pfizer will continue routine pharmacovigilance activities on behalf of BioNTech according to the Pharmacovigilance Agreement in place, in order to assure patient safety and will inform the Agency if an evaluation of the safety data yields significant new information for BNT162b2.

APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminasaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lambl's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

HEALTH

Miscarriage does not occur in 90% of vaccinated pregnant women

23 NOVEMBER 2021

WHAT WAS CLAIMED

Over 55,000 deaths have been caused by the Covid-19 vaccines.

OUR VERDICT

There seems to be no evidence for this claim, and reports of adverse events from the Yellow Card Scheme and VAERS make clear that reported reactions are not necessarily the result of the vaccine.

1 of 2 claims

A video featuring former University College Dublin professor Dolores Cahill and Dr Anne McCloskey, a GP who was suspended by the Health and Social Care Board in Northern Ireland and the Medical Practitioners Tribunal Service pending investigation, has been widely shared on Facebook. The video, which has been viewed over 49,000 times, includes false information about the Covid-19 vaccines.

We have fact checked two of the most important claims in the video, however the Facebook video includes other pieces of misleading information.

We have fact checked other claims made by Dr Cahill before.

False claims that the Yellow Card scheme and Vaccine Adverse Event Reporting System (VAERS) system provide definitive proof of adverse events and deaths

In the video, Dr Cahill claims that she and Dr McCloskey looked at the “actual evidence” from the “original sources” of information “like the Yellow Card system, or the adverse events that are reported in the Centres for Disease Control in America”. She says that using this information they can “definitively say that these clinical trials [...] have the most harm, adverse events and deaths from any clinical trials in history”. They say that there have been over 55,000 deaths in the “clinical trials”.

However, the Yellow Card scheme in the UK and the Vaccine Adverse Event Reporting System (VAERS) system in America are systems set up so that any adverse effects or side effects experienced around the time of vaccination (or other medications in the case of the Yellow Card scheme) can be reported by clinicians and members of the public. Such reports can then be monitored, reviewed and investigated as necessary.

Both the VAERS and Yellow Card systems are clear to explain that the reported symptoms are not necessarily caused by the vaccine.

The weekly summary of Yellow Card reporting for the Covid-19 vaccines produced by the Medicines and Healthcare products Regulatory Agency (MHRA) for example, says: “The nature of Yellow Card reporting means that reported events are not always proven

side effects".

It also says: "A Yellow Card report does not necessarily mean the vaccine caused that reaction or event".

In any case, Full Fact was not able to identify anywhere near 55,000 reports of deaths to the Yellow Card Scheme or VAERs system. For example, up to 10 November there have been 1,784 reports of deaths around the time of Covid-19 vaccination to the Yellow Card Scheme.

The MHRA states that the majority of these reports were "in elderly people or people with underlying illness".

Up to 15 November VAERS received 9,810 reports of death among people who had received a Covid-19 vaccine. around the time of Covid-19 vaccine.

In the phase three safety and efficacy trials, published by Pfizer, AstraZeneca and Moderna, there were five deaths reported among people who received the vaccine, and these deaths were from a variety of different causes. Data collection on long term protection and safety will continue to be collected over the coming years.

Video repeats false claims that "over 90%" of women who are pregnant and vaccinated in early pregnancy go on to have a miscarriage

The Facebook video also suggests that the babies of "over 90% of women who are pregnant and get this injection [the Covid-19 vaccines]" are "born dead" in the first 12 weeks, and say that the "foetal loss is huge".

The video doesn't state where this claim comes from. However, we have previously written about the misuse of data from a New England Journal of Medicine study to make the false claim that 82-91% of participants vaccinated in the first trimester of pregnancy went on to experience a miscarriage.

The MHRA says: "The numbers of reports of miscarriage and stillbirth are low in relation to the number of pregnant women who have received COVID-19 vaccines to date (more than 96,000 up to end of September 2021 in England and Scotland) and how commonly these events occur in the UK outside of the pandemic.

"There is no pattern from the reports to suggest that any of the COVID-19 vaccines used in the UK, or any reactions to these vaccines, increase the risk of miscarriage or stillbirth."

The NHS says: "There's no evidence the COVID-19 vaccines have any effect on your chances of becoming pregnant. There's no need to avoid getting pregnant after being vaccinated."

We have written more about false claims made regarding the Covid-19 vaccines and risk of miscarriage previously.

This article is part of our work fact checking potentially false pictures, videos and stories on Facebook. You can read more about this—and find out how to report Facebook content—here. For the purposes of that scheme, we've rated this claim as false Because the VAERS system and the Yellow Card scheme are to report suspected side effects or adverse events, they are not necessarily reactions that are caused by the vaccines. Claims that 90% of women vaccinated in early pregnancy go on to miscarry are false.

HEALTH / CORONAVIRUS

Vaccine deaths are not higher than Covid-19 deaths

6 AUGUST 2021

WHAT WAS CLAIMED

Official data shows twice as many people have died due to the Covid-19 vaccines in six months than people who have died of Covid-19 in 15 months.

OUR VERDICT

This is completely untrue, and is based on misleading conclusions drawn from official data. It only counts Covid-19 deaths in England with no underlying conditions, and misuses reports of deaths after Covid-19 vaccines where no causal link can be proven.

An article claiming that twice as many people have died from the Covid-19 vaccines in six months than have died from the virus itself throughout the entire pandemic has been reshared by a number of websites.

This is not true. The “official data” the articles cite has been misleadingly presented to reach an incorrect conclusion.

Covid-19 deaths

As we have written before, it’s impossible to compare the number of Covid-19 deaths and deaths reported after a dose of a Covid-19 vaccine as they are counted completely differently. The articles not only ignore this context, they also draw false conclusions about the data itself.

The articles are based on the premise that the only true Covid-19 deaths are ones where those people who died had no underlying conditions. From the start of the pandemic to 9 June there had been 3,591 such deaths in England.

This is an extremely misleading way of interpreting the data. “Underlying conditions” covers a broad range of health conditions, such as asthma, kidney disease and dementia, and doesn’t indicate whether or not Covid-19 was the leading cause of death.

We do have data on whether or not Covid-19 was the underlying cause of death, or whether someone died with Covid, but not from it. Figures from the Office for National Statistics show that over the course of 2021 so far 58,757 people in England and Wales have had Covid-19 mentioned on their death certificate, of those people 51,243 (87%) had it listed as the underlying cause of death.

Vaccines

In order to ascertain how many deaths have been reported after the Covid-19 vaccines, the author adds together the fatal adverse reactions across the UK reported to the Medicines and Healthcare products Regulatory Agency’s (MHRA) Yellow Card scheme up to 30 June. This came to 1,440.

As we have written before, the Yellow Card scheme relies on voluntary reporting from medics and members of the public, and is intended to provide an early warning of any previously unknown risks from medicines or medical devices.

However, an adverse event that occurs after vaccination did not necessarily occur because of it.

As the MHRA explains: “The nature of Yellow Card reporting means that reported events are not always proven side effects. Some events may have happened anyway, regardless of vaccination.

“This is particularly the case when millions of people are vaccinated, and especially when most vaccines are being given to the most elderly people and people who have underlying illness.”

With vaccines given to the most elderly and vulnerable first, it’s to be expected that a number of people would have coincidentally died in the period after being given their first dose.

The article also claims that, between 8 December 2020 and 11 June 2021, a total of 5,522 people in Scotland died within 28 days of having a dose of a Covid-19 vaccine.

This is based on data released by Public Health Scotland (PHS) and is true, but the articles misinterpret these deaths as deaths due to the vaccine.

As the PHS report clearly states: “The analysis includes all recorded deaths due to any cause and does not refer to deaths caused by the vaccine itself.”

It also adds that “the observed number of deaths is lower than expected compared with mortality rates for the same time period in previous years”.

The articles then add the figure of 5,522 deaths within 28 days of a Covid-19 vaccine dose from Scotland to the number of deaths reported through the Yellow Card scheme to say that “there have been 6,962 deaths in the past 6 months due to the Covid-19 vaccines”, and claim this is “almost double the number of people who have died of Covid-19 in England in the past 15 months”.

As we have set out above, this miscalculation rests entirely on an inaccurate understanding of Covid-19 death figures and deaths reported after a Covid-19 vaccine.

It also makes a false comparison between Covid-19 deaths with no underlying conditions in England alone, Yellow Card reports covering the entire UK and additional data from Scotland—which means some reported deaths could be double-counted.

The articles also make misleading claims about PCR tests used to detect Covid-19 in patients, stating: “The test used is the PCR test, which cannot detect infection and can find anything it wants to find if conducted at a high cycle rate, producing false positives.”

This is untrue, and we have written about similar claims before. At higher cycles, PCR tests are more likely to detect low levels of virus. This could, for example, indicate someone is at the start or end of their infection. It doesn’t mean they are “false positives”.

This article is part of our work fact checking potentially false pictures, videos and stories on Facebook. You can read more about this—and find out how to report Facebook content—here. For the purposes of that scheme, we’ve rated this claim as false because the articles misleadingly present data about Covid-19 deaths and deaths after vaccines to make false claims.

ASA Ruling on Stacey Bradley

Upheld | Newspaper | 25 May 2022

Background

Summary of Council decision:

Three issues were investigated, all of which were Upheld.

Ad description

Two local press ads in The Rotherham Advertiser and the digital version of The Argus, placed by Stacey Bradley:

a. The ad in The Rotherham Advertiser, published on 13 January 2022, featured large text at the top of the page that stated “NATIONAL EMERGENCY” and, at the bottom of the page, “THE TRUTH IS OUT”, both situated prominently on red and yellow striped banners. The main body of the ad featured the heading “CRIMINAL INVESTIGATION” accompanied by the logo of The Metropolitan Police Service and the text “CRIME NUMBER 6029679/21”. Further text stated “Related crimes and threats to the public health, gross negligent manslaughter and misconduct in the public office. A further 18 offences have also been cited including murder, fraud, GBH and multiple breaches of the Nuremburg Code”. Smaller text in red font stated “See: www.saveusnow.org/covid-vaccine-scientific-proof-lethal”. A further heading stated “Do you have information to help?” with the sub-heading “THIS IS NOT TO MAKE FINANCIAL CLAIMS FOR INJURY FROM THE COVID-19 VACCINE” also in red. Further text stated “Have you lost a loved one due to the Covid Vaccine? Do you suffer headaches, bloodclots [sic], blindness, heart issues, strokes or myocarditis since the Covid 19 vaccine? We’d also like to hear from those illegally threatened with ‘No Jab, No Job’”. Underneath, large prominent red text stated “Bayliss of Broad Yorkshire Law – loisbayliss@broadyorkshirelaw.co.uk”, followed by the crest of the South Yorkshire Police accompanied by the text “South Yorkshire POLICE”. Further smaller text stated “PLEASE IMMEDIATELY REPORT ANY COVID-19 VACCINE INJURIES & DEATHS INCLUDING ANY UNDUE INFLUENCE TO TAKE THE INJECTION INCLUDING ‘NO JAB / NO JOB’”.

b. The ad in the digital version of The Argus, published 21 January 2022, had the same content and layout as ad (a) except that it included a QR code and a different URL to that included in ad (a): “See: https://coronavirus-yellowcard.mhra.gov.uk/”. The ad featured the crest of South Yorkshire Police, but the accompanying text stated “POLICE” only.

Issue

Six complainants, including Full Fact, an independent fact-checking organisation, challenged whether the ads:

1. misleadingly implied they had been placed, approved or endorsed by public bodies including police forces such as The Metropolitan Police Service (MPS) and South Yorkshire Police (SYP);

2. misleadingly implied that vaccinations against COVID-19 were unsafe and illegal, and that police forces were currently undertaking a criminal investigation into the administration of COVID-19 vaccinations in the UK; and

3. were harmful and socially irresponsible.

Response

1., 2. & 3. Stacey Bradley acknowledged the complaint and provided a link to an article in a local newspaper reporting that an individual had died after receiving the COVID-19 vaccine.

The Rotherham Advertiser, who published ad (a), told us that they would not run the ad or similar ads in future. They had assured each police force that they would not publish any ads that featured their logos without permission.

They believed that the ad’s implication that vaccines were unsafe was not necessarily misleading given that some people experienced adverse reactions to them. They also believed that the ad’s publication was consistent with their newspaper’s commitment to offering a balanced view on current issues. They stated that the UK’s COVID-19 vaccine roll-out had been ongoing for some time by the time of the ad’s publication. As such, they believed that readers would have already come to their own views on vaccinations through other sources of information or by being vaccinated themselves. On that basis, they did not believe that it was harmful or irresponsible. They also stated that it was unlikely that the ad’s content shocked readers for the same reason.

The Argus, who published ad (b), did not respond to our enquiries.

Assessment

1. Upheld

The ASA considered that the use of the MPS and SYP logos gave readers the impression that the ads had been placed, approved, or endorsed by those police forces. We further considered that other elements of each ad, such as the heading that stated "CRIMINAL INVESTIGATION", the crime reference number and other references to "crimes" and "offences", the request for information about and reports of adverse reactions to the vaccine or "undue influence to take the injection" and the large text that stated "POLICE" at the bottom of the ads supported that impression.

The heading "NATIONAL EMERGENCY" appeared in large text at the top of each ad. Both ads also featured bright yellow and red stripes that were suggestive of 'emergency' markings used in UK Government ads placed throughout the pandemic in promotion of public health measures. We considered that those elements gave readers the impression that the ads were official communications from a public body. We further considered that the link to the MHRA website included in ad (b) contributed to that effect.Stacey Bradley did not provide any evidence that they had received authorisation from any public body. Further, we understood that neither police force had given the advertiser permission to use their logo, and that they had not been otherwise aware of, or involved in, the ads' creation. We therefore concluded that the ads misleadingly implied they were placed, approved or endorsed by public bodies when they were not.

On that point, ads (a) and (b) breached CAP Code (Edition 12) rules **3.1** (Misleading advertising) and **3.50** (Endorsements and testimonials).

2. Upheld

We considered that the heading "CRIMINAL INVESTIGATION", the police force logos, crime reference number and the text in the ads' copy referring to criminal offences and reference to people being "illegally threatened with 'No Jab, No Job'" were likely to give readers the impression that UK police forces were investigating the legality of the UK's COVID-19 vaccine roll-out. We noted that neither MPS nor SYP had launched any criminal investigation into the UK government's administration of COVID-19 vaccines. Further, MPS had publicly explained that their crime reference numbers should not be taken as evidence of an ongoing criminal investigation as they were issued upon receipt of every complaint. We considered the ad therefore misleadingly implied that police forces were undertaking a criminal investigation into the administration of COVID-19 vaccinations in the UK.

Both ads claimed that "threats to the public health, gross negligent manslaughter", "murder" and "GBH" had been involved in the administration of the vaccine. They also listed possible adverse reactions under the text "Have you lost a loved one due to the Covid Vaccine?". Ad (a) also included the URL "www.saveusnow.org/covid-vaccine-scientific-proof-lethal". We considered that those elements of the ads were likely to give readers the impression that the vaccine was unsafe.

Ad (b) included the URL for the Medicines and Healthcare products Regulatory Agency's (MHRA) Coronavirus Yellow Card site, where any suspected adverse reactions to the vaccine could be reported. We considered, when seen in context below the list of alleged crimes, that the inclusion of the URL in the ad gave the impression that data collected via the Yellow Card Scheme supported that the vaccine caused high numbers of injuries and fatalities. However, we noted the MHRA had stated that a report to the Yellow Card Scheme should not be interpreted as a proven effect of the vaccine.

The MHRA required that, prior to their approval, COVID-19 vaccines met strict evidential standards for safety and efficacy in several stages of clinical trials. We also understood that side-effects and adverse reactions associated with approved vaccines were continually monitored by the MHRA through various means. As such, we understood that the public body with relevant expertise considered that the vaccine was safe and effective.

Because we considered the ads gave the overall impression that vaccine was unsafe and illegal, we concluded that they were misleading.

On that point, ads (a) and (b) breached CAP Code (Edition 12) rule **3.1** (Misleading advertising).

3. Upheld

We considered that the implication in the ads that COVID-19 vaccines were unsafe and that the vaccine programme was illegal had the effect of encouraging vaccine hesitancy. Further, because the ads gave the impression of being placed, approved or endorsed by public bodies, we considered readers were likely to pay greater attention and place greater trust in the ads' message. Because of that, we considered the ads were unduly alarming and caused fear of COVID-19 vaccines without justifiable reason. We considered there was therefore a risk that the ads would discourage readers from being vaccinated. Because that could result in less protection for them and for the population more widely, we concluded that the ads were socially irresponsible.

On that point, ads (a) and (b) breached CAP Code (Edition 12) rules **1.3** (Social responsibility) and **4.2** (Harm & offence).

Action

The ads must not appear again in the form complained of. We told Stacey Bradley that their future ads must not misleadingly imply they had been placed, endorsed, or approved by a public body, including by unauthorised use of their logos. We also told them not to misleadingly imply that COVID-19 vaccinations were unsafe, including by implying that the MHRA Yellow Card Scheme was evidence that the vaccines were unsafe. Neither should they misleadingly imply that COVID-19 vaccinations were illegal,

including by implying that a crime reference number was evidence of an ongoing criminal investigation. We also told Stacey Bradley to ensure that their future ads were socially responsible and did not cause fear without justifiable reason.

CAP Code (Edition 12)

1.3 **3.1** **3.50** **4.2**

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ASA Ruling on Steven Thomas

Upheld | 02 February 2022

Background

Summary of Council decision:

Four issues were investigated, all of which were Upheld.

Ad description

A local press ad placed by Steven Thomas, seen in the Forest of Dean and Wye Valley Review, The Forester and the Cheltenham Post in September and October 2021 featured the headline “Do you know about the MHRA Yellow Card Scheme?” with the sub-headline “Have you been vaccinated or know somebody who has? Did you know that ANYONE can use the Yellow Card Scheme to report ANY suspected side-effects of the vaccine?”.

Text in the main body of the ad stated, “There are NO long-term studies on the effects of the Covid vaccine, so your reports are vital for the future vaccine safety of others”. Below that was a table titled “UK: Covid Vaccine Injury & Death Reports to 29th Sep 21”. At the top of the table was large, bold text that stated “INJURIES: 1,222,565 … DEATHS: 1,698”, with the words “INJURIES” and “DEATH” appearing in red, followed by a table which listed various medical conditions and the number of incidences of injuries and deaths allegedly attributable to the conditions caused by each of the three available COVID-19 vaccines. A table at the bottom of the ad listed alleged vaccine-related injury and death figures for the UK, EU and USA.

A bar running down the side of the ad stated, “REMEMBER … mRNA vaccines have never previously been used on humans … The phase 3 Coronavirus/Covid-19 vaccine trails end in 2033 meaning these ‘vaccines’ are experimental … Covid vaccines have not been approved for public use and have been authorised for emergency use only … The vaccine companies cannot be sued for any harm caused”.

Issue

Full Fact, an independent fact checking-organisation, challenged whether:1. the ad misleadingly presented the Yellow Card Scheme report data as the number of injuries and deaths that were caused by COVID-19 vaccines;2. the claim “Covid vaccines have not been approved for public use” was misleading and could be substantiated;3. the ad misleadingly implied the ad had been approved or endorsed by the Medicines and Healthcare products Regulatory Authority (MHRA); and4. the ad was socially irresponsible.

Response

1. Steven Thomas said that the data presented in the ad had been taken directly from the MHRA Yellow Card Scheme website and relevant reports on the side effects of the COVID-19 vaccines, referenced in the ad. Their understanding was that the Yellow Card Scheme was the official database for vaccine injuries in the UK and a report to the Scheme meant there had been a very strong suspicion, often submitted by a medical practitioner, that the vaccine was the cause. They said it followed that a “death” reported as part of the Scheme in relation to COVID-19 vaccines would always mean that the relative or doctor of the deceased believed to that to have been the cause of death.2. Steven Thomas said that all COVID-19 vaccines had been issued under an emergency use authorisation. They understood that no vaccine could achieve full approval for public use until Phase three trials had been completed, and that Phase three trials of the vaccines were ongoing and would not be completed until 2023.3. Steven Thomas said that they did not believe the ad contained any implication that it had been approved by the MHRA.4. Steven Thomas said that they were impartial and had placed the ad out of a sense of obligation to the public, drawing their attention to the process for reporting injuries.1. – 4. Tindle News t/a The Forester and the Forest of Dean and Wye Valley Review said that they had withdrawn the ad as a result of a small number of reader complaints and had turned down further, similar ads from other individuals.All4One Media Ltd t/a The Cheltenham Post said that the ad was part of an awareness campaign by Steven Thomas regarding the COVID-19 vaccines. They said Steven Thomas wanted to make readers aware of the MHRA Yellow Card Scheme, but that in the future they would consider similar advertising requests more carefully.

Assessment

1. UpheldThe ASA considered that readers would understand the claims “INJURIES: 1,222,565” and “DEATHS: 1,698” in the ad to mean the COVID-19 vaccines listed in the ad had directly caused those numbers of injuries and deaths, respectively. We considered that the claim “EVEY REPORT HELPS SAVE LIVES” and the detailed table shown in the ad contributed to that impression.We understood that a report to the MHRA Yellow Card Scheme of suspected side effects relating to the COVID-19 vaccines did not establish that they had caused the reaction or event reported. Such reports could be made by patients or healthcare professionals. We understood that many suspected adverse reactions reported via the Yellow Card Scheme did not have any causal relationship with the vaccines and that it was often coincidental that symptoms occurred around the same time as vaccination. In their explanatory note to the report data, the MHRA emphasised the importance of not interpreting suspected adverse reactions described in it as being proven side effects of COVID-19 vaccines.We

considered that the ad misrepresented the meaning of reports to the Yellow Card Scheme and we therefore concluded that the ad was misleading.On that point, the ad breached CAP Code (Edition 12) rules **3.1** (Misleading advertising) and **3.7** (Substantiation).2. UpheldWe considered that readers would understand the claim "Covid vaccines have not been approved for public use" to mean that the Government body responsible for ensuring vaccines were safe for public use had not yet approved the vaccines.We understood that the Department of Health and Social Care, through its executive agency the MHRA, had initially approved the COVID-19 vaccines listed in the ad – Oxford/AstraZeneca, BioNTech/Pfizer and Moderna – for public use under Regulation 174 of the Human Medicines Regulations 2012, and that Conditional Marketing Authorisations (CMAs) had since been granted for each vaccine. We understood that Regulation 174 authorisations and CMAs were both regulatory tools that enabled medicines to be approved at the earliest possible time during emergency situations, and that approval was given based on robust data.We therefore concluded that the claim "Covid vaccines have not been approved for public use" was misleading and had not been substantiated.On that point, the ad breached CAP Code (Edition 12) rules **3.1** (Misleading advertising) and **3.7** (Substantiation).3. UpheldWe considered that consumers would understand from the claim "Do you know about the MHRA Yellow Card Scheme?", which featured the same logo and colour scheme as the MHRA Scheme, that the ad had been placed, or authorised, by the MHRA. We considered that the inclusion of a link to the Yellow Card Scheme website, along with the claim "'EVERY REPORT HELPS SAVE LIVES'" in quotations contributed to that impression.Steven Thomas did not provide any evidence that he had received authorisation from the MHRA to place the ad, and the MHRA told us that they had not been involved in the ad's creation. We therefore concluded that the ad was misleading.On that point, the ad breached CAP Code (Edition 12) rules **3.1** (Misleading advertising) and **3.50** (Endorsements and testimonials).4. UpheldThe words "INJURIES" and "DEATHS" appeared in capital letters with a bold, red typeface, both at the top and the bottom of the ad in a table that showed a comparison of alleged deaths and injuries between the UK, the EU and the USA. We considered that presentation of the figures was alarmist in tone, and omitted the context provided by the MHRA's explanatory note to the publication referenced in the ad – namely that a report to the Yellow Card Scheme should not be interpreted as a proven effect of the vaccines. Text superimposed over the ad stated "MHRA estimate that only 1-10% of injuries are reported in the UK", which we considered was intended to give the impression that the figures presented in the ad were underestimates, and contributed to the alarmist nature of the ad.We also considered that the other claims featured in the ad, "REMEMBER … mRNA vaccines have never previously been used on humans … The phase 3 Coronavirus/Covid-19 vaccine trails end in 2023 meaning these 'vaccines' are experimental … Covid vaccines have not been approved for public use and have been authorised for emergency use only … The vaccine companies cannot be sued for any harm caused" cast significant doubt on the safety and efficacy of the vaccines. This, therefore, had the effect of encouraging vaccine hesitancy, and risked dissuading readers from having the COVID-19 vaccine.Given the risk that people could be discouraged from being vaccinated, based on reading the ad's claims, resulting in less protection for them and for the population more widely, we concluded that the ad was irresponsible.On that point, the ad breached CAP Code (Edition 12) rules **1.3** (Social responsibility).

Action

The ad must not appear again in the form complained of. We told Steven Thomas that their future ads must not present MHRA Yellow Card Scheme report data in a misleading way; misleadingly state that COVID-19 vaccines have not been approved for public use; or misleadingly imply that their ads have been endorsed or approved by the MHRA. We also told Steven Thomas to ensure that their future ads were socially responsible.

BCAP Code

1.3 **3.1** **3.7** **3.50**

CAP Code (Edition 12)

1.3 **3.1** **3.7** **3.50**

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Editorials

Wakefield's article linking MMR vaccine and autism was fraudulent

BMJ 2011; 342 doi: https://doi.org/10.1136/bmj.c7452 (Published 06 January 2011) Cite this as: BMJ 2011;342:c7452

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Clear evidence of falsification of data should now close the door on this damaging vaccine scare

"Science is at once the most questioning and . . . sceptical of activities and also the most trusting," said Arnold Relman, former editor of the *New England Journal of Medicine*, in 1989. "It is intensely sceptical about the possibility of error, but totally trusting about the possibility of fraud."[1] Never has this been truer than of the 1998 *Lancet* paper that implied a link between the measles, mumps, and rubella (MMR) vaccine and a "new syndrome" of autism and bowel disease.⇓

EARLY REPORT

Early report

Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

A J Wakefield, S H Murch, A Anthony, J Linnell, D M Casson, M Malik, M Berelowitz, A P Dhillon, M A Thomson, P Harvey, A Valentine, S E Davies, J A Walker-Smith

Summary

Background We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder.

Methods 12 children (mean age 6 years (range 3-10), 11 boys) were referred to a paediatric gastroenterology unit with a history of normal development followed by loss of acquired skills, including language, together with diarrhoea and abdominal pain. Children underwent gastroenterological, neurological, and developmental assessment and review of developmental records. Ileocolonoscopy and biopsy sampling, magnetic-resonance imaging (MRI), electroencephalography (EEG), and lumbar puncture were done under sedation. Barium follow-through radiography was done where possible. Biochemical, haematological, and immunological profiles were examined.

Findings Onset of behavioural symptoms was associated, by the parents, with measles, mumps, and rubella vaccination in eight of the 12 children, with measles infection in one child, and otitis media in another. All 12 children had intestinal abnormalities, ranging from lymphoid nodular hyperplasia to aphthoid ulceration. Histology showed patchy chronic inflammation in the colon in 11 children and reactive ileal lymphoid hyperplasia in seven, but no granulomas. Behavioural disorders included autism (nine), disintegrative psychosis (one), and possible postviral or vaccinal encephalitis (two). There were no focal neurological abnormalities and MRI and EEG tests were normal. Abnormal laboratory results were significantly raised urinary methylmalonic acid compared with age-matched controls (p=0·003), low haemoglobin in four children, and a low serum IgA in four children.

Interpretation We identified associated gastrointestinal disease and developmental regression in a group of previously normal children, which was generally associated in time with possible environmental triggers.

Lancet 1998; **351:** 637–41
See Commentary page 611

Introduction

We saw several children who, after a period of apparent normality, lost acquired skills, including communication. They all had gastrointestinal symptoms, including abdominal pain, diarrhoea, and bloating and, in some cases, food intolerance. We describe the clinical findings, and gastrointestinal features of these children.

Patients and methods

Clinical investigations

Laboratory investigations

THE LANCET • Vol 351 • February 28, 1998 637

Authored by Andrew Wakefield and 12 others, the paper's scientific limitations were clear when it appeared in 1998.[2] [3] As the ensuing vaccine scare took off, critics quickly pointed out that the paper was a small case series with no controls, linked three common conditions, and relied on parental recall and beliefs.[4] Over the following decade, epidemiological studies consistently found no evidence of a link between the MMR vaccine and autism.[5] [6] [7] [8] By the time the paper was finally retracted 12 years later,[9] after forensic dissection at the General Medical Council's (GMC) longest ever fitness to practise hearing,[10] few people could deny that it was fatally

flawed both scientifically and ethically. But it has taken the diligent scepticism of one man, standing outside medicine and science, to show that the paper was in fact an elaborate fraud.

In a series of articles starting this week, and seven years after first looking into the MMR scare, journalist Brian Deer now shows the extent of Wakefield's fraud and how it was perpetrated (doi:10.1136/bmj.c5347). Drawing on interviews, documents, and data made public at the GMC hearings, Deer shows how Wakefield altered numerous facts about the patients' medical histories in order to support his claim to have identified a new syndrome; how his institution, the Royal Free Hospital and Medical School in London, supported him as he sought to exploit the ensuing MMR scare for financial gain; and how key players failed to investigate thoroughly in the public interest when Deer first raised his concerns.[11]

Deer published his first investigation into Wakefield's paper in 2004.[12] This uncovered the possibility of research fraud, unethical treatment of children, and Wakefield's conflict of interest through his involvement with a lawsuit against manufacturers of the MMR vaccine. Building on these findings, the GMC launched its own proceedings that focused on whether the research was ethical. But while the disciplinary panel was examining the children's medical records in public, Deer compared them with what was published in the *Lancet*. His focus was now on whether the research was true.

The Office of Research Integrity in the United States defines fraud as fabrication, falsification, or plagiarism.[13] Deer unearthed clear evidence of falsification. He found that not one of the 12 cases reported in the 1998 *Lancet* paper was free of misrepresentation or undisclosed alteration, and that in no single case could the medical records be fully reconciled with the descriptions, diagnoses, or histories published in the journal.

Who perpetrated this fraud? There is no doubt that it was Wakefield. Is it possible that he was wrong, but not dishonest: that he was so incompetent that he was unable to fairly describe the project, or to report even one of the 12 children's cases accurately? No. A great deal of thought and effort must have gone into drafting the paper to achieve the results he wanted: the discrepancies all led in one direction; misreporting was gross. Moreover, although the scale of the GMC's 217 day hearing precluded additional charges focused directly on the fraud, the panel found him guilty of dishonesty concerning the study's admissions criteria, its funding by the Legal Aid Board, and his statements about it afterwards.[14]

Furthermore, Wakefield has been given ample opportunity either to replicate the paper's findings, or to say he was mistaken. He has declined to do either. He refused to join 10 of his coauthors in retracting the paper's interpretation in 2004,[15] and has repeatedly denied doing anything wrong at all. Instead, although now disgraced and stripped of his clinical and academic credentials, he continues to push his views.[16]

Meanwhile the damage to public health continues, fuelled by unbalanced media reporting and an ineffective response from government, researchers, journals, and the medical profession.[17] [18] Although vaccination rates in the United Kingdom have recovered slightly from their 80% low in 2003-4,[19] they are still below the 95% level recommended by the World Health Organization to ensure herd immunity. In 2008, for the first time in 14 years, measles was declared endemic in England and Wales.[20] Hundreds of thousands of children in the UK are currently unprotected as a result of the scare, and the battle to restore parents' trust in the vaccine is ongoing.

Any effect of the scare on the incidence of mumps remains in question. In epidemics in the UK, the US, and the Netherlands, peak prevalence was in 18-24 year olds, of whom 70-88% had been immunised with at least one dose of the MMR vaccine.[21] [22] Any consequence of a fall in uptake after 1998 may not become apparent until the cohorts of children affected reach adolescence. One clue comes from an outbreak in a school in Essen, Germany, attended by children whose parents were opposed to vaccinations. Of the 71 children infected with mumps, 68 had not been immunised.[23]

But perhaps as important as the scare's effect on infectious disease is the energy, emotion, and money that have been diverted away from efforts to understand the real causes of autism and how to help children and families who live with it.[24]

There are hard lessons for many in this highly damaging saga. Firstly, for the coauthors. The GMC panel was clear that it was Wakefield alone who wrote the final version of the paper. His coauthors seem to have been unaware of what he was doing under the cover of their names and reputations. As the GMC panel heard, they

did not even know which child was which in the paper's patient anonymised text and tables. However, this does not absolve them. Although only two (John Walker-Smith and Simon Murch) were charged by the GMC, and only one, the paper's senior author Walker-Smith, was found guilty of misconduct, they all failed in their duties as authors. The satisfaction of adding to one's CV must never detract from the responsibility to ensure that one has been neither party to nor duped by a fraud. This means that coauthors will have to check the source data of studies more thoroughly than many do at present—or alternatively describe in a contributor's statement precisely which bits of the source data they take responsibility for.

Secondly, research ethics committees should not only scrutinise proposals but have systems to check that what is done is what was permitted (with an audit trail for any changes) and work to a governance procedure that can impose sanctions where an eventual publication proves this was not the case. Finally, there are lessons for the Royal Free Hospital, the *Lancet*, and the wider scientific community. These will be considered in forthcoming articles.

What of Wakefield's other publications? In light of this new information their veracity must be questioned. Past experience tells us that research misconduct is rarely isolated behaviour.**25** Over the years, the *BMJ* and its sister journals *Gut* and *Archives of Disease in Childhood* have published a number of articles, including letters and abstracts, by Wakefield and colleagues. We have written to the vice provost of UCL, John Tooke, who now has responsibility for Wakefield's former institution, to ask for an investigation into all of his work to decide whether any more papers should be retracted.

The *Lancet* paper has of course been retracted, but for far narrower misconduct than is now apparent. The retraction statement cites the GMC's findings that the patients were not consecutively referred and the study did not have ethical approval, leaving the door open for those who want to continue to believe that the science, flawed though it always was, still stands. We hope that declaring the paper a fraud will close that door for good.

Notes

Cite this as: *BMJ* 2011;342:c7452

Footnotes

- Feature, doi:10.1136/bmj.c5347
- Competing interests: All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years. HM chairs GMC fitness to practise panels. He had no association with the Wakefield hearings and the views expressed in this article are his own and do not represent those of the GMC.
- Provenance and peer review: Commissioned; not externally peer reviewed.

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