



Medicines & Healthcare products  
Regulatory Agency



## **Coronavirus Vaccine - summary of Yellow Card reporting**

Data included: 9/12/2020 to 8/09/2021

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# Summary

At the time of this report, over 134,045 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 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 is now](#) 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.

The 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's role is also to continually monitor 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.

This safety update report is based on detailed analysis of data up to 8 September 2021. At this date, an estimated 22.1 million first doses of the Pfizer/BioNTech vaccine and 24.8 million first doses of the COVID-19 Vaccine AstraZeneca had been administered, and around 18.7 million and 23.9 million second doses of the Pfizer/BioNTech vaccine and COVID-19 Vaccine AstraZeneca respectively. An approximate 1.4 million first doses and approximately 1 million second doses of the COVID-19 Vaccine Moderna have also now been administered.

As of 8 September 2021, for the UK, 113,312 Yellow Cards have been reported for the Pfizer/BioNTech vaccine, 231,161 have been reported for the COVID-19 Vaccine AstraZeneca, 15,565 for the COVID-19 Vaccine Moderna and 1074 have been reported where the brand of the vaccine was not specified.

For the Pfizer/BioNTech, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna the overall reporting rate is around 3 to 6 Yellow Cards per 1,000 doses administered.

In the week since the previous summary for 1 September 2021 we have received a further 1,995 Yellow Cards for the Pfizer/BioNTech vaccine, 662 for the COVID-19 Vaccine AstraZeneca, 486 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 vaccinations as many factors can influence ADR reporting.

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.

### **Severe allergy**

On 9 December 2020, the MHRA issued preliminary guidance on severe allergic reactions after the Pfizer/BioNTech vaccine due to early reports of anaphylaxis. Following further detailed review, this advice was amended on 30 December to the [current advice](#). This advice is that people with a previous history of severe allergic reactions to any ingredients of the vaccine should not receive it. People who receive the vaccine should be monitored for at least 15 minutes afterwards.

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

### **Blood clots with concurrent low platelets**

The MHRA has undertaken a thorough review into UK reports 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 is also considering other blood clotting cases (thromboembolic events) alongside low platelet levels.

This ongoing scientific review has concluded that the evidence of a link with COVID-19 Vaccine AstraZeneca is stronger and [an announcement](#) was made on 7 April 2021 with a further statement on 7 May. We have continued to publish the latest breakdown of all cases of these extremely rare

side effects on a weekly basis. In this report we provide updated information on cases received up to 8 September 2021. Our advice remains unchanged.

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 their second dose. Anyone who did not have these side effects should come forward for their second dose when invited.

The MHRA recently confirmed that the evidence to date does not suggest that the COVID-19 Vaccine AstraZeneca causes venous thromboembolism without a low platelet count.

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 is getting 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.

## **Conclusion**

- Vaccines are the best way to protect people from COVID-19 and have already saved thousands of lives. Everyone should continue to get their vaccination when asked to do so unless specifically advised otherwise.
- As with all vaccines and medicines, the safety of COVID-19 vaccines is being continuously monitored.
- Cases of an extremely rare specific type of blood clot with low blood platelets continue to be investigated.

Further information on the type of suspected adverse reactions (ADRs) reported for the COVID-19 mRNA 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.

# 1. 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 has played 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 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 they both occurred around the same time. 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 mRNA Pfizer/BioNTech](#), [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 Pfizer/BioNTech, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna), and MHRA's analysis of the data, **between 9 December 2020 and 8 September 2021 (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.



## 2. Yellow Card reports

### Vaccine doses administered

Data from the UK [Public Health agencies](#) show that at least 48,344,566 people have received their first vaccination in the UK by 8 September 2021, with 43,708,906 second doses administered. The priority groups of the immunisation campaign for this period included people aged 16 years and over, the clinically vulnerable, care home residents and workers, and frontline health and social care workers.

**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 8 September 2021.**

Country	Number of doses
England	40,551,671
Wales	2,364,393
Northern Ireland	1,294,896
Scotland	4,133,606

**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 8 September 2021.**

Country	Number of doses
England	36,571,165
Wales	2,195,417
Northern Ireland	1,184,987
Scotland	3,757,337

As of 8 September, an estimated 22.1 million first doses of the Pfizer/BioNTech vaccine and 24.8 million first doses of the COVID-19 Vaccine AstraZeneca had been administered, and around 18.6 million and 23.9 million second doses of the Pfizer/BioNTech vaccine and COVID-19 Vaccine AstraZeneca respectively. An approximate 1.4 million first doses and approximately 1 million second doses of the COVID-19 Vaccine Moderna have also now been administered. 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 as vaccinations given are recorded on the relevant system. Therefore, data for this may be incomplete and the resulting estimates approximate.

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

### 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. 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.

Up to and including 8 September 2021, the MHRA received and analysed 113,312 UK Yellow Cards from people who have received the Pfizer/BioNTech vaccine. These reports include a total of 320,570 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 8 September 2021, the MHRA received and analysed a total of 231,161 UK reports of suspected ADRs to the COVID-19 Vaccine AstraZeneca. These reports include a total of 823,202 suspected reactions (a single report may contain more than one symptom). The first report was received on 4 January 2021.

Up to and including 8 September 2021, the MHRA received and analysed a total of 15,565 UK reports of suspected ADRs to the COVID-19 Vaccine Moderna. These include a total 49,771 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 8 September 2021, the MHRA received 1074 Yellow Card reports where the brand of vaccine was not specified by the reporter.

In the week since the previous summary for 1 September 2021 we have received a further 1,995 Yellow Cards for the Pfizer/BioNTech vaccine, 662 for the COVID-19 Vaccine AstraZeneca, 486 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 vaccinations as many factors can influence ADR reporting.

**Table 3: Number of suspected ADR reports received in the UK up to and including 8 September 2021.**

Country	Number of reports			
	Pfizer/ BioNtech	Oxford University/ AstraZeneca	Moderna	Brand unspecified
England	87,715	191,527	12,915	623
Wales	5,765	10,192	428	62
Northern Ireland	2,199	2,795	39	10
Scotland	8,916	16,327	1,573	119

The figures in Table 3 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 is in the order of 3 to 6 Yellow Cards per 1,000 doses administered for the 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).

## 3 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 vaccine 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 national epidemic, and because many of the millions of people offered the vaccine in the early phase of a vaccination campaign are elderly and/or have 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. 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, and this is discussed below.

We also take into account the international experience based on data from other countries using the same vaccines.

### Overall safety

As with any vaccine, the COVID-19 vaccines will cause side effects in some people. The total number and the nature of Yellow Cards reported 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 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 are building 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.

## **Comments on specific reports**

The following reports reflect data up to 8 September 2021. The glossary provides an explanation of the clinical terms used.

### **Anaphylaxis (Severe allergic reactions)**

The MHRA continues to monitor reports of serious allergic reactions with the Pfizer/BioNTech vaccine and has received 482 UK spontaneous adverse reactions associated with anaphylaxis or anaphylactoid reactions. The nature and frequency of these reports is in line with that reported in previous updates, and severe allergic reactions to the 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 39 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.

The MHRA also closely monitors reports of anaphylaxis or anaphylactoid reactions with the COVID-19 Vaccine AstraZeneca and has received 816 UK spontaneous adverse reactions associated with anaphylaxis or anaphylactoid reactions reported and is very rare. An update to the product information has been made to reflect the fact that cases of anaphylaxis have been reported for the COVID-19 Vaccine AstraZeneca.

## **Bell's Palsy**

MHRA continues to review cases reporting Bell's Palsy and to analyse case reports against the number expected to occur by chance in the absence of vaccination (the 'natural rate'). The number of reports of facial paralysis received so far is similar to the expected natural rate and does not currently suggest an increased risk following the vaccines. We will continue to monitor these events, including through evaluation of electronic healthcare record data.

## **Thrombo-embolic events with concurrent low platelets**

Up to 8 September 2021, the MHRA had received Yellow Card reports of 419 cases of major thromboembolic events (blood clots) with concurrent thrombocytopenia (low platelet counts) in the UK following vaccination with COVID-19 Vaccine AstraZeneca. Forty five of the 416 reports have been reported after a second dose. Of the 419 reports, 211 occurred in women, and 204 occurred in men aged from 18 to 93 years. The overall case fatality rate was 17% with 72 deaths, six of which occurred after the second dose.

Cerebral venous sinus thrombosis was reported in 150 cases (average age 46 years) and 269 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 8 September was 24.8 million and the estimated number of second doses was 23.9 million.

The overall incidence after first or unknown doses was 15.1 per million doses. Taking into account the different numbers of patients vaccinated with COVID-19 Vaccine AstraZeneca in different age groups, the data shows that there is a higher reported incidence rate in the younger adult age groups following the first dose compared to the older groups (20.7 per million doses in those aged 18-49 years compared to 10.8 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 16.3 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 after second doses was 1.9 cases per million doses. Taking into account the different numbers of patients vaccinated with COVID-19 Vaccine AstraZeneca in different age groups, the data shows that there is a lower reported incidence rate in younger adult age groups following the second dose compared to the older groups (0.9 per million doses in those aged 18-49 years compared to 1.9 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 15.9 million second doses have been given to patients aged 50+ years. These rates 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 at this stage, 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 reports have also been analysed by the Government's independent advisory body, the 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 4: Number of suspected thrombo-embolic events with concurrent thrombocytopenia ADR reports received for the COVID-19 Vaccine AstraZeneca in the UK up to and including 8 September 2021.**

Country	Number of reports
England	327
Wales	13
Northern Ireland	10
Scotland	35
Unknown	34

**Table 5: Number of UK suspected thrombo-embolic events with concurrent thrombocytopenia ADR reports received for the COVID-19 Vaccine AstraZeneca by patient age up to and including 8 September 2021.**

Age range (years)	Number of reports	Number of fatal reports
18-29	28	7
30-39	50	11
40-49	105	12
50-59	100	19
60-69	60	9
70-79	39	7
80-89	6	3
90-99	2	1
Unknown	29	3
<b>Total</b>	<b>419</b>	<b>72</b>

**Table 6: Number of UK suspected thrombo-embolic events with concurrent thrombocytopenia ADR reports received for the COVID-19 Vaccine AstraZeneca by patient sex up to and including 8 September 2021.**

Sex	Number of reports	Number of fatal reports
Male	204	31
Female	211	41
Unknown	4	0
<b>Total</b>	<b>419</b>	<b>72</b>

Up to 8 September 2021, the MHRA had received Yellow Card reports of 18 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 6 women, and 11 men aged from 28 to 91 years, and the overall case fatality rate was 12% with two deaths reported.

Up to 8 September 2021, the MHRA had received Yellow Card reports of 2 cases of major thromboembolic events (blood clots) with concurrent thrombocytopenia (low platelet counts) in the UK following the use of COVID-19 vaccine Moderna. The 2 events occurred in adult males under the age of 50, and 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. 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.

### **Capillary Leak Syndrome**

The MHRA has received 12 reports of capillary leak syndrome (a condition where fluid leaks from the small blood vessels into the body) in the context of more than 48.8 million doses of COVID-19 Vaccine AstraZeneca given. Of these reports, 2 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 Commission on Human Medicines' 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.

A total of 34,633 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 27,199 individual Yellow Card reports (as each report may contain more than one suspected reaction). This is following approximately 47.8 million COVID-19 vaccine doses administered to women up to 8 September 2021. 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.

### **Safety of COVID-19 vaccines in pregnancy**

The MHRA closely monitors the safety of COVID-19 vaccine exposures in pregnancy, including Yellow Card reports for COVID-19 vaccines used in pregnancy. These reports have been reviewed by the independent experts of the Commission on Human Medicines' 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 should be offered to those who are pregnant at the same time as non-pregnant individuals based on their age and clinical risk group. The Pfizer/BioNTech and Moderna vaccines are currently the preferred vaccines for use during pregnancy.

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 72,000) 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. 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). Stillbirths are sadly estimated to occur in about 1 in 200 pregnancies in the UK. A few reports of commonly occurring congenital anomalies and preterm births have also been received. There is no pattern from the reports to suggest that any of the COVID-19 vaccines used in the UK increase the risk of congenital anomalies or birth complications.

Pregnant women have reported similar suspected reactions to the vaccines as people who are not pregnant.

Like most vaccines and medicines, clinical trials of COVID-19 vaccine in pregnant women were not carried out prior to use of the vaccines in the general population. However, evidence from non-clinical studies of the COVID-19 vaccines available in the UK 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. Extensive international experience for the Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna used in pregnancy have also not raised any safety concerns.

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.

### **Safety of COVID-19 vaccines in 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 Commission on Human Medicines' 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 3,000 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.

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/>.

### **Myocarditis and pericarditis (Inflammation of the heart)**

Up to and including 8 September 2021, we have received 275 reports of myocarditis and 205 reports of pericarditis following use of the Pfizer/BioNTech vaccine, as well as four reports for viral pericarditis, three reports of carditis, two reports for infective pericarditis and one report each of viral myocarditis, non-infective endocarditis and streptococcal endocarditis. For COVID-19 Vaccine AstraZeneca there have been 105 reports of myocarditis and 162 reports of pericarditis following vaccination up to and including 8 September 2021 as well as five reports for viral pericarditis, three reports of endocarditis, two reports for endocarditis bacterial and carditis and one report each for viral myocarditis, infectious myocarditis and acute endocarditis. There have been 53 reports of myocarditis, 40 reports of pericarditis and one report of endocarditis following use of COVID-19 Vaccine Moderna up to the same date.

In the UK the overall reporting rate for myocarditis (including viral myocarditis), after both first and second dose, is 6.8 cases per million doses of Pfizer/BioNTech and for pericarditis (including viral pericarditis and infective pericarditis) the overall reporting rate is 5.2 cases per million doses of Pfizer/BioNTech. For Moderna, the overall reporting rate for myocarditis is 21.6 per million doses and for pericarditis is 16.3 per million doses. For AstraZeneca the overall reporting rate for myocarditis (including viral myocarditis and infectious myocarditis) is 2.2 per million doses and for pericarditis (including viral pericarditis) is 3.4 per million doses.

Myocarditis and pericarditis happen very rarely in the general population, and it is estimated that in the UK there are about 6 new cases of myocarditis per 100,000 patients per year and about 10 new cases of pericarditis per 100,000 patients per year.

The MHRA has undertaken a thorough review of both UK and international reports of myocarditis and pericarditis following vaccination against COVID-19. There has been a recent increase in reporting of these events in particular with the Pfizer/BioNTech and Moderna vaccines, with a consistent pattern of cases occurring more frequently in young males and shortly after the second dose of the vaccines. These reports are extremely rare, and the events are typically mild with individuals usually recovering within a short time with standard treatment and rest. People should come forward for their first and second vaccination when invited to do so, unless advised otherwise.

These reports have also been analysed by the Government's independent advisory body, the Commission on Human Medicines (CHM) and its COVID-19 Vaccines Benefit Risk Expert Working Group. Following their advice, the product information for the Moderna and Pfizer/BioNTech vaccines have been updated to inform of these cases and advise healthcare professionals and patients to be aware of important symptoms for myocarditis and pericarditis.

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

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.

### **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 Moderna vaccine 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 has been known to be associated with COVID-19 infection as well as other infectious diseases.

Up to and including the 8 September 2021, the MHRA has received 403 reports of Guillain-Barré Syndrome with the COVID-19 Vaccine AstraZeneca and 24 reports of a related disease called Miller Fisher syndrome. Up to the same date, the MHRA has received 48 reports of Guillain-Barre Syndrome following use of the Pfizer/BioNTech vaccine and for the COVID-19 Vaccine Moderna there have been three reports of Guillain-Barré Syndrome.

The MHRA has been closely monitoring and assessing cases of Guillain-Barré Syndrome reported following administration of the COVID-19 vaccines and based on the available evidence, we are not able to confirm or rule out a causal relationship with the vaccines. Following advice from the government's independent advisory body, the Commission on Human Medicines (CHM) and its COVID-19 Vaccines Benefit Risk Expert Working Group, the product information for the COVID-19 Vaccine AstraZeneca has been updated to include a precautionary warning that Guillain-Barré Syndrome has very rarely been reported following vaccination.

The MHRA will continue to review cases of Guillain-Barré Syndrome reported following vaccination with COVID-19 vaccines to further assess a possible association between Guillain-Barré Syndrome and COVID-19 vaccines, 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 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 cases of facial swelling occurring 1-2 days after vaccination in vaccine recipients with a history of injection of facial dermal fillers were reported 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 Pfizer/BioNTech vaccine. A recent review of the world-wide ADR data for the Pfizer/BioNTech vaccine found that, in most cases, the facial swelling was mild, transient and was localised to the site of the dermal filler. The product information for the 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. Fatal cases associated with extremely rare blood clots with lowered platelets are described above.

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.

The MHRA has received 526 UK reports of suspected ADRs to the Pfizer/BioNTech vaccine in which the patient died shortly after vaccination, 1,075 reports for the COVID-19 Vaccine AstraZeneca, 16 for the COVID-19 Vaccine Moderna and 28 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 indicate a link between vaccination and the fatalities reported. Review of individual reports and patterns of reporting does not suggest the vaccines played a role in these deaths.

A range of other isolated or series of reports of non-fatal, serious suspected ADRs have been reported. These all remain under continual review, including through 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.

## 4 Conclusion

At the time of this report, over 134,045 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 Pfizer/BioNTech vaccine, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna have demonstrated very high levels of protection against symptomatic infection. [Data is now](#) 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 so far 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.

Cases of an extremely rare specific type of blood clot with low blood platelets continue to be investigated and updated advice has been provided.

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 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 – Pfizer BioNTech

Vaccine Analysis Print - Oxford University/AstraZeneca

Vaccine Analysis Print - 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.

**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.

### **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 refers 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.

### **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.

### **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.