



Medicines & Healthcare products
Regulatory Agency

Coronavirus Vaccines

Summary of Yellow Card reporting for COVID-19 vaccines

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Data included up to and including 22 February 2023 for COVID-19 vaccines used from the beginning of Autumn 2022.

This information is also available on the [gov.uk](https://www.gov.uk) website



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Update on publication status

The Commission on Human Medicine (CHM) has advised that given the end of the Autumn 2022 booster campaign and the stable safety profile of the COVID-19 vaccines, the MHRA should transition to routine data publication and communication of safety concerns for COVID-19 vaccines. This report is therefore the last regular publication of the Summary of Yellow Card reporting for COVID-19 vaccines.

Robust safety monitoring and surveillance of any COVID-19 vaccines used in the UK will continue along with timely communication on any updated safety advice when needed. Additionally, monthly updates of Adverse Drug Reaction (ADR) data will continue with the new interactive [COVID-19 vaccine reports](#).

We would ask anyone who suspects they have experienced a side effect linked with their COVID-19 vaccine to report via the [Yellow Card website](#).

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Summary

Since January 2023, the MHRA revised the format of the Summary of Yellow Card reporting to focus on the COVID-19 vaccines administered from the beginning of the Autumn 2022 booster campaign. Any new assessments or safety issues regarding vaccines used in the primary and initial booster campaigns will also be included in this record, however previous and known information on these vaccines will remain available as a record only and can be viewed on the government website.

Over the course of the pandemic over 178,407 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 monovalent COVID-19 Vaccine Pfizer/BioNTech, COVID-19 Vaccine AstraZeneca and monovalent COVID-19 Vaccine Moderna – were used in the primary and booster vaccination campaigns up to the end of August 2022. Up to 23 August 2022, 53 million people received a first dose of COVID-19 vaccine, 50 million received a second dose and 40 million received a third or booster dose. Safety monitoring throughout the deployment showed that the most common adverse reactions for all the COVID-19 vaccines were mild and self-limiting 'reactogenicity'-type events such as fever, fatigue and injection site pain. View our [existing record](#) for a summary of information received via the Yellow Card scheme on these three vaccines as well as safety investigations carried out by the Medicines and Healthcare products Regulatory Agency (MHRA) on these products.

On 15 August and 3 September 2022 respectively, the Moderna bivalent vaccine (Spikevax bivalent Original/Omicron BA.1) and the Pfizer/BioNTech bivalent vaccine (Comirnaty Original/Omicron BA.1) were approved by the MHRA as booster vaccines in those aged 12 years and above. Both bivalent vaccines are active against the original strain of the SARS-CoV-2 virus and the Omicron BA.1 variant. COVID-19 vaccine Novavax (Nuvaxovid), approved by the MHRA on 3 February 2022, and indicated for use in those aged 12 years and above is also being used as a booster dose in the small proportion of patients who are unable to receive mRNA vaccines.

All COVID-19 vaccines used in the autumn 2022 UK booster programme have been authorised for supply by the MHRA following a thorough review of quality and immunogenicity data in line with international regulatory standards. In trials, these vaccines elicited strong antibody responses to the SARS-CoV-2 virus and to variants of concern, sufficient to protect against COVID-19. [Data](#) are available on the impact of the vaccination campaign in reducing infections, illness and mortality in the UK.

On 3 September 2022 the Joint Committee on Vaccination and Immunisation (JCVI) issued a [statement](#) describing which COVID-19 vaccines would be used for those eligible to receive an autumn COVID-19 vaccine booster.

All vaccines and medicines have some side effects although not everybody gets them. These side effects need to be continuously balanced against the expected benefits in preventing illness. As part of the MHRA's responsibility to ensure that the benefits of the COVID-19 vaccines used in the UK continue to outweigh the risks, the MHRA is closely monitoring the bivalent mRNA vaccines and COVID-19 vaccine Novavax using the [proactive pharmacovigilance surveillance strategy](#) in place for the initial vaccine rollout. 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. Our ongoing review of suspected adverse events following the launch of the National Autumn 2022 booster campaign has not revealed any new safety concerns.

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 22 February 2023, for the UK, 4,096 Yellow Cards have been reported for the bivalent COVID-19 Vaccine Pfizer/BioNTech, 5,108 for the bivalent COVID-19 Vaccine Moderna, 57 for the COVID-19 Vaccine Novavax and 2,319 have been reported where the brand of the vaccine was not specified (please note this may also include vaccines which were used in the primary and initial booster campaign where the brand was not reported).

For both the bivalent COVID-19 Vaccine Pfizer/BioNTech, and bivalent COVID-19 Vaccine Moderna the overall reporting rate is around 0.5 Yellow Cards per 1,000 doses administered. There is insufficient experience with COVID-19 Vaccine Novavax to be able to make similar estimates of reporting rates.

It is important to note that Yellow Card data cannot be used to derive side-effect rates or compare the safety profile of different 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 by the MHRA throughout the pandemic in relation to both monovalent and bivalent vaccines, 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 the Section titled Analysis of data. The [previous summary](#) of COVID-19 Yellow Card reporting provides information on the monovalent vaccines used in the previous primary and initial booster campaign.

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 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.

The Yellow Card website, under [“What is being reported?”](#) provides further information on the type of suspected adverse reactions reported for all COVID-19 vaccines used throughout the pandemic. 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; however, as part of its statutory functions, the MHRA is responsible for monitoring all 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 as well as any 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 vaccines are provided in the product information document for healthcare professionals and in the UK Patient Information Leaflet (PIL).

[COVID-19 Pfizer/BioNTech bivalent \(BA.1\)](#)

[COVID-19 Vaccine Moderna bivalent \(BA.1\)](#)

[COVID-19 Vaccine Novavax](#)

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 COVID-19 vaccines currently in use in the UK following the launch of the National Autumn 2022 booster campaign (the bivalent COVID-19 Vaccine Pfizer/BioNTech, the bivalent COVID-19 Vaccine Moderna and COVID-19 Vaccine Novavax), and the MHRA's analysis of the data, up to and including 22 February 2023 (inclusive). A glossary of key terms is provided in Annex 2.

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

Yellow Card reports

Vaccine doses administered in the Autumn 2022 booster campaign

Everyone aged 5 years and over is eligible to receive a first and second dose of a COVID-19 vaccine. People aged 16 years and over, and some children aged 12 to 15, are also eligible to receive a booster dose. People aged 5 years and over who had a severely weakened immune system when they had their first 2 doses, will be offered a third dose before any booster doses. People aged 50 years and older, residents in care homes for older people, those aged 5 years and over in a clinical risk group and health and social care staff will be offered an autumn booster of a COVID-19 vaccine.

For the Autumn 2022 COVID-19 vaccination booster campaign, the bivalent COVID-19 Pfizer/BioNTech booster vaccine (Comirnaty Original/Omicron BA.1) and the bivalent COVID-19 Moderna booster vaccine (Spikevax bivalent Original/Omicron) are mainly being used. The original monovalent Pfizer-BioNTech vaccine is recommended for eligible persons aged 5-11 years while the COVID-19 vaccine Novavax (Nuvaxovid) is recommended for those who cannot receive an mRNA vaccine.

As of 22 February 2023, an estimated 40,622,659 people had received their third dose and/or at least one booster dose in the UK. Note that a patient may have received multiple booster doses, but they will only be counted once in this figure. People aged 16 and over, and some children aged 12 to 15, are eligible to receive a booster dose. An estimated 33.1 million third or booster doses of monovalent COVID-19 Vaccine Pfizer/BioNTech, 60,900 third or booster doses of COVID-19 Vaccine AstraZeneca and 13.3 million third or booster doses of monovalent COVID-19 Vaccine Moderna have been given. An approximate 11.5 million booster doses of bivalent COVID-19 Vaccine Pfizer/BioNTech and approximately 9.3 million booster doses of bivalent COVID-19 Vaccine Moderna had also been administered. Approximately 1,200 booster doses of COVID-19 Vaccine Novavax have been administered.

Vaccination data are not always reported weekly and can be updated for historical dates when vaccinations are recorded on the relevant system, therefore the data 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.

Table 1: Number of people who have received at least one third or booster dose of a vaccine for COVID-19 in the UK between 8 December 2020 and 22 February 2023¹

Country	Number of people who have received a third or any booster dose
England	33,905,464
Wales	2,076,578
Northern Ireland	1,045,782
Scotland	3,594,835

Yellow Card reporting trends for vaccines administered in the Autumn 2022 booster campaign

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.

From 1 September 2022 to 22 February 2023, the MHRA received and analysed 4,096 UK Yellow Cards from people who have received the bivalent COVID-19 Vaccine Pfizer/BioNTech. These reports include a total of 10,867 suspected reactions (i.e., a single report may contain more than one symptom).

From 1 September 2022 to 22 February 2023, the MHRA received and analysed a total of 5,108 UK reports of suspected ADRs to the bivalent COVID-19 Vaccine Moderna. These

¹ As a result of changes to the publication schedules of vaccine usage data, Table 1 captures data from the date closest to our data lock point. This table includes data from England up to 19 February 2023, Wales up to 14 February 2023 and Northern Ireland up to 22 February 2023, and Scotland up to 4 September 2022. The estimated 40,622,659 people who had received a 3rd or any booster dose was derived from the numbers in Table 1.

include a total 13,896 suspected reactions (a single report may contain more than one symptom).

From 1 September 2022 to 22 February 2023, the MHRA received and analysed a total of 57 UK reports of suspected ADRs to the COVID-19 Vaccine Novavax. These include a total of 178 suspected reactions (a single report may contain more than one symptom).

Up to 22 February 2023, the MHRA received 2,319 Yellow Card reports where the brand of vaccine was not specified by the reporter. Please note this may also include vaccines used in the primary and initial booster campaign where the brand of vaccine was not reported.

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

Table 2: Number of suspected ADR reports received in the UK up to and including 22 February 2023.

Country	Number of reports		
	COVID-19 Vaccine Pfizer/ BioNTech (Bivalent)	COVID-19 Vaccine Moderna (Bivalent)	COVID-19 Vaccine Novavax
England	3421	3897	28
Wales	237	400	^
Northern Ireland	40	26	0
Scotland	239	434	7

‘^’ Where there are less than 5 reports, numbers have been replaced with a ^ in order to prevent patient/reporter identification in line with our duty of confidentiality to patients and reporters.

The figures in Table 2 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 the vaccines as a 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 0.5 Yellow Cards per 1,000 doses administered for both the bivalent COVID-19 Vaccine Pfizer/BioNTech, and bivalent COVID-19 Vaccine Moderna. There is insufficient experience with COVID-19 Vaccine Novavax to be able to make similar estimates of reporting rates. 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 of the original 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.

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 in relation to both the monovalent and bivalent vaccines 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 specific safety topics can be found below. The [previous summary](#) of COVID-19 Yellow Card reporting provides MHRA assessment of safety topics relating to monovalent vaccines used in the previous primary and initial booster campaign.

In addition to the specific safety topics summarised in this report, a range of other isolated events or series of reports of 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.

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 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 become 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 and can be given at any stage in pregnancy.

Pregnant women have reported similar suspected reactions to the original vaccines as people who are not pregnant. The COVID-19 vaccines do not contain organisms that can multiply in the body, so they cannot infect an unborn baby in the womb. There is no pattern from Yellow Card reports or published studies (^{2 3 4 5 6 7}) to suggest that any of the original COVID-19 vaccines used in the UK, or any reactions to these vaccines, increase the risk of miscarriage, stillbirths, congenital anomalies or birth complications. The [previous summary](#) of COVID-19 Yellow Card reporting provides full details of safety in pregnancy for monovalent vaccines used in the previous primary and initial booster campaign.

² Kharbanda EO, et al. Spontaneous abortion following COVID-19 vaccination during pregnancy. JAMA. doi:10.1001/jama.2021.15494:

<https://jamanetwork.com/journals/jama/fullarticle/2784193>

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:

<https://www.nejm.org/doi/10.1056/NEJMc2114466>

⁴ Stock SJ, et al Early pregnancy outcomes following COVID-19 vaccination and SARS-CoV-2 infection: a national population-based matched cohort study

<https://www.researchsquare.com/article/rs-1955486/v1>

⁵ Public Health Scotland, COVID-19 Statistical report:

<https://publichealthscotland.scot/publications/covid-19-statistical-report/covid-19-statistical-report-11-may-2022/>

⁶ 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> .

⁷ Goldshtein et al Association of BNT162b2 COVID-19 Vaccination During Pregnancy With Neonatal and Early Infant Outcomes JAMA Pediatrics (2022)

doi:[10.1001/jamapediatrics.2022.0001](https://doi.org/10.1001/jamapediatrics.2022.0001)

No differences in safety are expected for the bivalent vaccines. Nevertheless, the MHRA will continue to closely monitor safety data following use of the COVID-19 vaccines in pregnancy, including through evaluation of electronic healthcare record data.

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.

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.

Yellow Card reports received from women breastfeeding at the time of vaccination with either the original or bivalent vaccines have mostly 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.

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. For the National Autumn 2022 booster campaign, the monovalent and bivalent (original/Omicron BA.1) Pfizer/BioNTech vaccines were recommended for eligible people aged 12-17 years and the monovalent Pfizer/BioNTech vaccine was recommended for those aged 5 to 11 years. The experience with COVID-19 vaccines reported in individuals under 18 years old is similar to that identified in the general population and to date no additional

safety topics specific to this age group have been identified. We will continue to closely monitor the safety of the COVID-19 vaccines in those under 18 years old.

Comments on specific safety topics

The following section reflects areas of ongoing assessment across monovalent and bivalent vaccines. Details on any safety topics not included below and the assessment of these may be included in the [previous summary](#) of COVID-19 Yellow Card reporting. The glossary provides an explanation of the clinical terms used.

Menstrual disorders (period problems) and unexpected vaginal bleeding

The MHRA has continued to review 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. Evidence from the most recent review suggested a possible association between the Pfizer and Moderna COVID-19 vaccines and heavy menstrual bleeding. The events were mostly non-serious and were temporary in nature. The product information for the Pfizer and Moderna COVID-19 vaccines has been updated to add heavy menstrual bleeding as a possible side effect. The rigorous evaluation completed to date does not support a link between COVID-19 vaccines and other changes to menstrual periods. 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.

From 1 September 2022 to 22 February 2023 a total of 182 suspected reactions relating to a variety of menstrual disorders have been reported after administration of the bivalent COVID-19 vaccines or COVID-19 vaccine Novavax including heavier than usual periods, delayed periods and unexpected vaginal bleeding. These suspected reactions have been reported in 167 individual Yellow Card reports (as each report may contain more than one suspected reaction). This is following approximately 1.7 million bivalent COVID-19 vaccine doses administered to women under 50 years of age up to 22 February 2023. 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 MHRA will continue 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 both the monovalent COVID-19 Vaccine 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 both monovalent COVID-19 Vaccine Moderna and COVID-19 Vaccine Pfizer/BioNTech was updated to inform healthcare professionals and patients of these reports and provide advice to be aware of important symptoms for myocarditis and pericarditis. This advice has also been included in the product information for the bivalent (original/Omicron BA.1) COVID-19 vaccines for Moderna and Pfizer/BioNTech.

Myocarditis and pericarditis have also been reported rarely following vaccination with COVID-19 Vaccine Novavax and a warning about this risk is included in its product information.

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.

Reporting rates of suspected myocarditis and pericarditis after bivalent COVID-19 vaccine Pfizer/BioNTech and bivalent COVID-19 vaccine Moderna are presented below. These reporting rates may also be subject to change as more experience is gathered in the UK. There is currently insufficient data to calculate a reliable estimate of the reporting rate of myocarditis and pericarditis in the UK for COVID-19 vaccine Novavax.

Table 3: Reporting rates per million doses for UK ADR reports of suspected myocarditis and pericarditis associated with bivalent COVID-19 vaccines, by patient age and dose, up to and including 22 February 2023.

Age range (years)	COVID-19 vaccine Pfizer/BioNTech (Bivalent)	COVID-19 Vaccine Moderna (Bivalent)
Under 18	*	*
18-29	21	**
30-39	18	**
40-49	**	**
50-59	5	**
60-69	2	5
70+	2	2

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

**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.

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.

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

Reports 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 including those with a fatal outcome will occur, especially given the millions of people vaccinated.

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 (ONS) death registrations, several thousand deaths are expected to have occurred naturally, mostly in the elderly, within 7 days of the many millions of doses of vaccines administered so far.

For reference, weekly death registrations within England, Wales, Scotland and Northern Ireland are available from relevant statistical authorities. The most recent data during the preparation of the summary of Yellow Card reporting is summarised as follows:

- England and Wales ([ONS](#)): In the week ending 10 February 2023, 12,672 deaths were registered; of these deaths, 446 cited COVID-19, accounting for 3.5% of all deaths.
- Scotland ([The National Records of Scotland](#)): In the week ending 19 February 2023, 1,263 deaths were registered; of these deaths, 48 cited COVID-19, accounting for 3.8% of all deaths.
- Northern Ireland ([The Northern Ireland Statistics and Research Agency](#)): In the week ending 17 February 2023, 402 deaths were registered; of these deaths, 12 cited COVID-19, accounting for 3.0% of all deaths.

The MHRA takes all reports with a fatal outcome in patients who have received a COVID-19 vaccine very seriously and every report with a fatal outcome is reviewed carefully. All reports with a fatal outcome regardless of the time period between receiving the suspect vaccine and the reported death are reviewed. All available information is assessed to consider whether the vaccine may have caused the reported death. Cumulatively, the Yellow Card data is thoroughly analysed for patterns or evidence which might suggest a causal link between the vaccination and the reported death alongside data available from international sources. This is further considered by the Commission on Human Medicines and its Expert Advisory Groups.

The MHRA has received 30 UK reports of suspected ADRs with a fatal outcome to the bivalent COVID-19 Pfizer/BioNTech vaccine and 42 reports of suspected ADRs with a fatal

outcome for the bivalent COVID-19 vaccine Moderna. The MHRA has received no UK reports with a fatal outcome for COVID-19 Vaccine Novavax.

A report with a fatal outcome 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 UK reports with a fatal outcome are subject to many factors that influence ADR reporting. They should therefore not be used to directly compare the safety of the different vaccines.

Previous summaries of Yellow Card reporting covering the primary and Autumn 2021 booster vaccination campaigns presented tabulated summaries of reports with a fatal outcome stratified by vaccine brand, age and sex. With respect to the use of bivalent COVID-19 vaccines and the Autumn 2022 booster campaign these tables have now been replaced with an [interactive search tool](#) to allow readers to view the total number of reports with a fatal outcome received by the MHRA across the UK primary and booster vaccination programmes. The tool presents data by vaccine brand, age and sex with respect to these reports with a fatal outcome.

Reports with a fatal outcome are concentrated in older age groups with decreasing numbers in younger age groups. This finding is consistent with data from the ONS outlining [weekly provisional figures on death registrations in England and Wales by sex and age group](#). As an example, in the week ending 12 February 2021 15,354 deaths were registered in England and Wales. In that week, 8,488 deaths (55.3%) occurred in those aged 80 years and older.

As the number of vaccine doses administered has increased, so has the number of reports with fatal outcomes following vaccination. However, this does not mean that there is a link between vaccination and the fatalities reported. The UK Health Security Agency has previously analysed the direct and indirect impact of the vaccination programme on infections and mortality. It has been estimated that up to 26 September 2021, the UK vaccination programme prevented between 23.9 and 24.3 million infections and between 123,600 and 131,300 deaths.

A [study](#) published by the ONS and the Office of 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, in the six weeks following COVID-19 vaccination. This is consistent with 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 will continue to carefully review and monitor all reports submitted to us including those that cite a fatal outcome following COVID-19 vaccination. When a safety issue is confirmed the MHRA will act promptly to inform patients and healthcare professionals and take appropriate steps to mitigate any identified risk.

Conclusion

Over the course of the pandemic over 178,407 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 and an autumn booster campaign for eligible patients was deployed from September 2022.

All COVID-19 vaccines used in the UK's Autumn 2022 booster programme have been authorised for supply by the Medicines and Healthcare products Regulatory Agency (MHRA) following a thorough review of quality and immunogenicity data in line with international regulatory standards. In trials, these vaccines elicited strong antibody responses to the SARS-CoV-2 virus and to variants of concern, sufficient to protect against COVID-19. [Data](#) are available on the impact of the vaccination campaign in reducing infections, illness and mortality 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 benefits of the vaccines in preventing COVID-19 and serious complications associated with COVID-19 far outweigh any currently known side effects. Whilst this is the final regular publication of the Summary of Yellow Card reporting, the safety of COVID-19 vaccines will be continuously monitored, and benefits and possible risks remain under review, as with all vaccines and medicines

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

Annex 1 – What is being reported

The Yellow Card website displays information on all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme for each of the COVID-19 vaccines. 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 which can 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 on our website alone.

When viewing the reports 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 on our database 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.

[COVID-19 Vaccine Pfizer/BioNTech monovalent](#)

[COVID-19 Vaccine Pfizer/BioNTech bivalent](#)

[COVID-19 Vaccine AstraZeneca](#)

[COVID-19 Vaccine Moderna monovalent](#)

[COVID-19 Vaccine Moderna bivalent](#)

[COVID-19 Vaccine - brand unspecified or not in routine use in the UK](#)

[COVID-19 Vaccine Novavax](#)

Annex 2 Glossary

Bivalent vaccine

A vaccine which stimulates an immune response to two viral strains.

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.

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.

Miscarriage

The loss of a pregnancy during the first 23 weeks.

Monovalent vaccine

A vaccine which stimulates an immune response to one viral strain.

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.

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.

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.