

Immunisation Clinical Advice Response Service 03/09/21

For any COVID-19 vaccination related queries or to escalate an incident please contact:
england.swicars@nhs.net

Please note that since Monday 2nd August CARS has now become ICARS and will operate from 9am - 5pm Monday to Friday.

**PLEASE SHARE WITH ALL RELEVANT STAFF INVOLVED WITH THE
VACCINATION PROGRAMME**

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Update on National Incident in Response to Reports Of Thrombosis with Thrombocytopenia Following Vaccination with the COVID-19 AstraZeneca Vaccine and Information on Reports of Myocarditis and Pericarditis, Guillain-Barre Syndrome and Menstrual Disorders Following COVID-19 Vaccination

Please see the attached document for full version and list of support resources

Background and Interpretation**1. Update on : Thrombosis with thrombocytopenia following vaccination with the COVID-19 AstraZeneca vaccine**

This briefing note is an update to the 7th May 2021 briefing note about the national incident response to reports of thrombosis with thrombocytopaenia (TTS) following the AstraZeneca (AZ) COVID-19 vaccine.

Based on reporting through the MHRA Yellow Card Scheme, as of 4th August 2021, there have been a total of 412 suspected cases of thromboembolic events occurring with thrombocytopenia across the UK following AZ vaccination, with 43 of these reported after the second dose, although most of these latter cases have not been confirmed. (1) Reporting of cases has slowed considerably in recent weeks with only 17 new suspected cases reported between 7th July and 4th August. This is likely to reflect the advice to preferentially use mRNA



vaccines in adults under 40 years. The overall incidence after first doses is estimated at 14.9 cases per million doses of vaccine with an overall case fatality rate of 18% (1).

Whilst investigation remains ongoing for some cases, it is important to note that the overwhelming majority of cases reported after the second dose have not been confirmed. Given an increasing number of second doses have been administered, it is reassuring that the reports of TTS remain dramatically lower than after the first dose and there is therefore no evidence of an association of this syndrome with the second dose of AstraZeneca vaccine. The JCVI advises that those who have received their first dose of the AZ vaccine should continue to be offered the second dose, unless they have developed this specific syndrome of thrombosis and thrombocytopenia following the first dose or if the vaccine is otherwise contraindicated.

Up to 4th August, the MHRA had received 15 reports of thrombosis events with low platelets following vaccination with the Pfizer/BioNTech vaccine and two reports following vaccination with Moderna vaccine. There is no evidence of a signal with either the Pfizer/BioNTech or Moderna vaccines with these cases likely to represent the background rate of this syndrome.

Case Reporting

It is important that all suspected cases continue to be reported to both the MHRA on the [COVID-19 Yellow Card scheme](https://cutt.ly/haem_AE) and to PHE's clinical reporting scheme at https://cutt.ly/haem_AE

Further advice for health professionals are available at <https://www.gov.uk/government/collections/covid-19-vaccination-and-blood-clotting>

2. Myocarditis and Pericarditis after COVID-19 vaccination

Cases of myocarditis and pericarditis have been reported following COVID-19 vaccination. This was first observed in Israel and USA where an increase in reporting was observed in young adult males typically within 6 days after receiving the second dose of either the Pfizer BioNTech or Moderna vaccines.

Myocarditis and pericarditis are inflammation of the heart muscle and the sac surrounding the heart respectively. They are typically rare in the population – in 2017 it was estimated that there were 2,000 hospital admissions in the UK for myocarditis. There are a variety of causes, including viral infections, and there have been reports of cases following COVID-19 infection. Cases of myocarditis are more common in men, with male cases tending to be younger than female cases. Most cases respond well to treatment and the prognosis is good, but it can progress to dilated cardiomyopathy and chronic heart failure, with evidence implicating it in 12% of sudden deaths in adults aged under 40. Pericarditis can have a similar presentation to myocarditis. The long-term prognosis of pericarditis is good, but it can become recurrent and rarely patients can develop constrictive pericarditis.

In the UK as at 4th August 2021, the MHRA has received: 165 reports of myocarditis and 140 reports of pericarditis following use of the Pfizer/BioNTech vaccine, 86 reports of myocarditis and 141 reports of pericarditis following use of the AZ vaccine, and 29 reports of myocarditis and 25 reports of pericarditis following use of the Moderna vaccine.

In the UK the overall reporting rate for myocarditis, after any dose, is 4.7 cases of myocarditis and 4.0 cases of pericarditis per million doses of Pfizer/BioNTech. For Moderna, the overall reporting rate for myocarditis is 15.9 per million doses and for pericarditis is 13.7 per million

doses. For AstraZeneca the overall reporting rate for myocarditis is 1.8 per million doses and for pericarditis is 3.0 per million doses. The low incidence reported after the AZ vaccine is likely to reflect the background rate.

Cases following vaccination are reported to have recovered from the acute episode with standard treatment, although ongoing clinical follow up of these cases remains critical to understand any potential long-term consequences.

In the USA where over 177 million people have received at least one dose of a COVID-19 vaccine, there have been 1,226 reports of myocarditis or pericarditis following vaccination with mRNA COVID-19 vaccination (Pfizer/BioNTech or Moderna vaccines). In those with reported myocarditis, the median age was 26 years and the median time to onset was 3 days after the vaccination. For those 1,212 individuals for which sex was known, 923 were male, and for those 1,094 individuals for which number of vaccine doses is known, 76% of cases had developed myocarditis after dose two. The CDC further analysed USA myocarditis data of in those aged under 30 years – 96% of cases were hospitalised but there were no deaths. In Israel, 275 cases of myocarditis were reported between December 2020 and May 2021, and a similar picture was seen with 95% of these cases reported to be mild.

The CDC, European Medicines Agency and the WHO have reviewed the available evidence and have concluded that the benefits of vaccination with mRNA vaccines continues to outweigh the risks.

Individuals should continue to come forward for vaccination, unless advised otherwise by a healthcare professional. The product information for the Pfizer/BioNTech and Moderna vaccines have been updated to inform of these cases and to inform healthcare professionals and individuals of the symptoms of myocarditis and pericarditis.

Clinical investigation and management

It is important to ensure all health professionals are alert to relevant symptoms which require further clinical review and investigation. Myocarditis and pericarditis present with new onset chest pain, shortness of breath or feelings of having a fast-beating, fluttering, or pounding heart. Anyone who develops these symptoms within one week following vaccination should urgently seek medical assistance.

Further information for healthcare professionals can be found here [[COVID-19 vaccination and rare side effects - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/covid-19-vaccination-and-rare-side-effects) and [Green Book](#)]. The patient information leaflet "[What to expect after your COVID-19 vaccination](#)" provides information on side-effects, including myocarditis and pericarditis symptoms. All suspected cases should be reported to the MHRA using the [COVID-19 Yellow Card scheme](#).

PHE will be collaborating on the ongoing investigation of this signal, and the national incident response will be expanded to include myocarditis /pericarditis. The existing incident team which includes MHRA /NHSEI will be expanded to include cardiological expertise,

2. Guillain-Barre Syndrome (GBS) post COVID-19 vaccination

A very small number of cases of GBS have been reported following COVID-19 vaccination. Guillain-Barré Syndrome is a very rare condition which causes inflammation and demyelination of the peripheral nerves leading to rapid onset of weakness. Paralysis is usually ascending and symmetrical, usually starting with the limbs and may then spread to the chest

and face. This condition has been associated with COVID-19 infection as well as other infectious diseases, most notably campylobacter infection.

The background reported incidence is 2 per 100, 000 per year; it increases with age and is more common in men. As of the 4th August 2021, there have been 377 reports of GBS following AZ vaccination and 22 reports of a related disease called Miller Fisher syndrome, 39 following Pfizer/BioNTech vaccination and 2 following Moderna vaccination. Over this time period, 20.46 million first doses and 13.8 second doses of the Pfizer/BioNTech have been administered, 24.8 million first doses and 23.6 million second doses of the AZ vaccines have been administered, and 1.3 million first doses and 0.4 million second doses of the Moderna vaccine. Work is ongoing to determine whether there is an association between receiving the COVID-19 vaccination and cases of GBS. As a precautionary measure, the MHRA will be adding a warning on Guillain-Barré Syndrome to the product information of the COVID-19 Vaccine AstraZeneca.

It is important that healthcare professionals are alert to the signs and symptoms of GBS so that suspected cases are provided with the appropriate care and treatment.

All suspected cases should be reported to the MHRA using the [COVID-19 Yellow Card scheme](#).

Menstrual disorders

MHRA have also issued more information on reports of menstrual disorders and vaginal bleeding following vaccination. The current evidence does not suggest an increased risk of either menstrual disorders or unexpected vaginal bleeding following vaccination with Pfizer/BioNTech, COVID-19 Vaccine AstraZeneca or COVID-19 Vaccine Moderna. There is also no evidence to suggest that COVID-19 vaccines will affect fertility.

<https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting#analysis-of-data>

Implications and recommendations for PHE Centres

PHE Centres are asked to note the updated information included in this briefing note. PHE Centres are requested to cascade this briefing note to local primary and secondary care services to ensure colleagues are aware of the latest available guidance and how to report suspected cases.

Implications and recommendations for PHE sites and services

PHE sites and services are asked to note the updated information in this briefing note.

Implications and recommendations for PHE Screening and Immunisation teams

An increase in calls requesting advice are expected. Screening and immunisation teams are requested to note the updated information and guidance. SITs are requested to cascade this briefing note to their local primary care teams.

Implications and recommendations for local authorities

Local Authorities are asked to note the updated information.

Recommendations for NHS trusts and COVID-19 immunisation services

Services are asked to ensure that anyone being offered an AZ COVID-19 vaccination is given the [COVID-19 vaccination and blood clotting guide](#) before vaccination. All people receiving any COVID-19 vaccine should be given the patient vaccination leaflet 'What to expect after vaccination' and know to seek appropriate healthcare assistance if required. These resources have been updated to reflect that latest guidance. All leaflets are available to order as paper copies and in other accessible formats including translations. Primary care services should be aware of these symptoms and refer to secondary care as appropriate following assessment.

References

(1)MHRA: Coronavirus vaccine -weekly summary ofYellow Cardreporting(updated 12th August2021)[Coronavirus \(COVID-19\) vaccine adverse reactions-GOV.UK \(www.gov.uk\)](#)

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