

Regional Clinical Advice Response Service 09/04/21

For any COVID-19 vaccination related queries or to escalate an incident please contact:
england.swcovid19-voc@nhs.net

Please note that going forward and in line with the RVOC and NVOC, RCARS will now operate between the hours of 8am and 6pm over the weekend.

PLEASE SHARE WITH ALL RELEVANT STAFF INVOLVED WITH THE VACCINATION PROGRAMME

Contents:

To access each of the items in the contents below, please press ctrl and click on the relevant link.

1. [Event National Incident in Response to Reports of Thrombosis with Thrombocytopenia Following Vaccination with the COVID-19 AstraZeneca Vaccine](#)
2. [Publication C1245: MHRA and JCVI Announcement Regarding AstraZeneca Vaccine and Next Steps 07/04/21](#)
3. [JCVI statement on Use of the AstraZeneca COVID-19 Vaccine: 7 April 2021](#)
4. [Press Release : MHRA Issues New Advice, Concluding a Possible Link Between COVID-19 Vaccine AstraZeneca and Extremely Rare, Unlikely to Occur Blood Clots](#)
5. [Reminder of Guidance on: COVID-19 Vaccination of Patients Aged Less Than 18 Years Old](#)
6. [Reminder of Guidance on: Vaccination Site SOP – Maternity Escalation Protocol](#)
7. [Reminder of Guidance on: Shared Learning - Denying Access to Treatment/Intervention](#)
8. [Reminder of Guidance on: Second Dose Vaccination](#)
9. [Supporting COVID-19 Vaccine Uptake During Ramadan](#)
10. [Use of Sedation for Those with Learning Difficulties.](#)

Event National Incident in Response to Reports of Thrombosis with Thrombocytopenia Following Vaccination with the COVID-19 AstraZeneca Vaccine

Serial number 2021/013 Date 07/04/2021

Notified by National Infection Service
Authorised by Mary Ramsay, Ruth Milton



Background and Interpretation

The AstraZeneca (AZ) COVID-19 vaccine was licensed for use in the UK on the 30th December 2020 and since the 4th January more than 20 million doses have been

administered across the UK. The COVID-19 programme in England has been estimated to have prevented 6,100 deaths in adults aged 70 years and older till the end of February with a vaccine effectiveness of a single dose against hospitalisation estimated at 80% both the Pfizer/BioNTech and the AZ vaccines (1).

As of 31st March, there have been 79 reports of thromboembolic events accompanied by thrombocytopenia, most notably a very rare and specific type of syndrome of blood clots in the cerebral veins, known as cerebral venous sinus thromboses (CVST) occurring together with

low platelet counts. These have affected patients of all ages and genders. The cases are unusual because despite thrombocytopenia, there is progressive thrombosis, primarily venous, including cerebral venous sinus thrombosis and portal vein thrombosis, as well as the more usual presentations of deep vein thrombosis and pulmonary embolism. Arterial events have

also been noted. Typical laboratory features include a low platelet count, very raised D-Dimer levels - above the level expected for venous thromboembolism (VTE) and inappropriately low fibrinogen. Antibodies to platelet factor 4 (PF4) have been identified and so this has similarities to heparin-induced thrombocytopenia (HIT), but in the absence of patient exposure to heparin treatment.

This is known to occur naturally although the underlying risk factors have not yet been fully established. The background rate of CVSTs is around 5-16 per million annually but there is currently limited data on the background rate of CVSTs with thrombocytopenia. It is currently estimated that the overall incidence following the AZ vaccine is around 4 per million first doses administered. Importantly thromboses are described in individuals with natural COVID-19 infection. More than a fifth of hospitalised patients with COVID-19 have evidence of blood clots, and the presence of these almost doubles the risk of death.

Based on a review of cases reported to the Yellow Card Scheme and the evidence of effectiveness of the COVID vaccines used in the UK to prevent serious complications and deaths from COVID-19 infection, the current MHRA advice remains that the overall benefits of the vaccine programme outweighs the extremely rare adverse events reported to date following the AZ vaccine.

The Joint Committee on Vaccination and Immunisation (JCVI) has assessed the overall risk benefit of the use of the AZ vaccine in the population. This is based on data presented by the MHRA on reported adverse events through the Yellow Card Scheme and benefits (in terms of deaths, ICU and hospital admissions averted) estimated by Public Health England. There appears to be a trend of increasing incidence of this condition with decreasing age amongst adults, with the highest incidence reported in the younger adult age groups. In contrast, the risks of serious disease associated with COVID-19 increases steeply with age, with the younger adults at the lowest risk of serious disease. Therefore, weighing the balance of benefits and risks, currently the JCVI has concluded that for adults under 30 years of age who are not in a clinical risk group, it is preferable to offer an alternative to the AZ vaccine if available.

In the UK, the MHRA are reviewing all reported cases to the COVID-19 Yellow Card scheme. In order to support the case reporting, clinical review and investigation, PHE has established

an electronic clinical reporting scheme collecting patient identifiable information on all suspected cases. All health professionals are encouraged to report any suspected case with details of the clinical presentation, dates of vaccination, vaccine product received and any underlying conditions. A data sharing process has been agreed with the MHRA which means that professionals only need to report suspected cases once through this scheme.

While the detailed case review is ongoing, it is important to ensure all health professionals are alert to relevant symptoms which require further clinical review and investigation. As the recommended management of this presenting condition differs from the usual guidance, urgent advice is being cascaded to primary care to ensure GPs are on the alert for this syndrome. It is therefore recommended that an urgent full blood count be considered in any patient presenting more than 4 days and within 28 days of coronavirus vaccination with:

- New onset of severe headache, which is getting worse and does not respond to simple painkillers
- An unusual headache which seems worse when lying down or bending over, or may be accompanied by blurred vision, nausea and vomiting, difficulty with speech, weakness, drowsiness or seizures
- New onset of unexplained pinprick bruising or bleeding
- Shortness of breath, chest pain, leg swelling or persistent abdominal pain

If you have any clinical concerns, patients should be urgently referred to hospital and to appropriate specialist services for further assessment, particularly if the symptoms are unexplained and present in combination with thrombocytopaenia. Further guidance for secondary care are available [here](#).

Mild flu-like symptoms, including headache, chills and fever remain one of the most common side effects of any COVID-19 vaccine. These generally appear within a few hours and resolve within a day or two. In order to support the ongoing investigation led by the MHRA, a national standard incident has been declared.

The role of the PHE incident response will be to support with:

- Case reporting and data collection
- Laboratory investigation of suspected cases including checking COVID antibody status
- Epidemiological investigation
- Communications – public and health professionals

Further information will be coming from PHE and other agencies including a CAS alert, updated SOPs, PGDs and a new Green Book chapter.

Implications and recommendations for PHE Centres

PHE Centres are asked to note the current information and guidance for primary and secondary care. PHE Centres are requested to cascade this briefing note to local primary and secondary care services to ensure colleagues are aware of the 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 current information and guidance for primary and secondary care.

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 current information and guidance. SITs are requested to cascade this briefing note which includes additional specific guidance developed for primary care with their local primary care teams. Additional resources will be published to support SITs in response to enquiries they may receive.

Implications and recommendations for local authorities

Local Authorities are asked to note the current information and guidance for primary and secondary care.

Recommendations for NHS trusts and COVID-19 immunisation services

Services are asked to ensure that people receiving a COVID-19 vaccine are given the patient vaccination leaflet 'COVID-19 vaccination and blood clotting information leaflet', which should accompany the usual 'COVID-19 adult leaflet version 4' before considering vaccination and then be given 'What to expect after vaccination version 4' after vaccination with their record card and know to seek appropriate healthcare assistance if required.

These resources have been updated to reflect that latest guidance. Primary care services should be aware of these symptoms and refer to secondary care as appropriate following assessment.

View the leaflets [here](#) and order them [here](#)

References and additional resources:

(1) PHE monitoring of the effectiveness of COVID-19 vaccination [PHE monitoring of the effectiveness of COVID-19 vaccination - GOV.UK \(www.gov.uk\)](#)

Sources of information

Coronavirus Yellow Card reporting site [Official MHRA side effect and adverse incident reporting site for coronavirus treatments and vaccines | Coronavirus \(COVID-19\)](#)

Public Health England: Thrombotic events with thrombocytopenia following immunisation to COVID-19 https://cutt.ly/haem_AE

Guidance produced from the Expert Haematology Panel (EHP) focussed on syndrome of Thrombosis and Thrombocytopenia occurring after coronavirus Vaccination Guidance produced from the Expert Haematology Panel (EHP) focussed on syndrome of Thrombosis and Thrombocytopenia occurring after coronavirus Vaccination | British Society for Haematology (b-s-h.org.uk) [Guidance produced from the Expert Haematology Panel \(EHP\) focussed on syndrome of Thrombosis and Thrombocytopenia occurring after coronavirus Vaccination | British Society for Haematology \(b-s-h.org.uk\)](#)

MHRA issues new advice, concluding a possible link between COVID-19 Vaccine AstraZeneca and extremely rare, unlikely to occur blood clots <https://www.gov.uk/government/news/mhra-issues-new-advice-concluding-a-possible-link-between-covid-19-vaccine-astrazeneca-and-extremely-rare-unlikely-to-occur-blood-clots>

Use of the AstraZeneca COVID-19 vaccine: JCVI statement <https://www.gov.uk/government/publications/use-of-the-astrazeneca-covid-19-vaccine-jcvi-statement> PHE Briefing Note 2021/013 Issued 07/04/2021

COVID-19 vaccination and blood clotting resources

<https://www.gov.uk/government/collections/covid-19-vaccination-and-blood-clotting>

Blood Clotting following COVID-19 Vaccination - Information for Health Professionals

<https://www.gov.uk/government/collections/covid-19-vaccination-and-blood-clotting>

Publication C1245: MHRA and JCVI Announcement Regarding AstraZeneca Vaccine and Next Steps 07/04/21

Dear colleague

We are writing to you following today's update from the Medicines and Healthcare product Regulatory Agency (MHRA) and the independent Joint Committee on Vaccination and Immunisation (JCVI) guidance in relation to the use of the AstraZeneca vaccine. The updated guidance has been published and can be found here:

<https://www.gov.uk/government/publications/use-of-the-astrazeneca-covid-19-vaccine-jcvi-statement/jcvi-statement-on-use-of-the-astrazeneca-covid-19-vaccine-7-april-2021>

The statement from the JCVI states:

"Since the start of the pandemic over 4 million COVID-19 infections have been confirmed in the UK causing more than 120,000 deaths. Over 30 million people have received their first dose of COVID-19 vaccine since the start of the programme, which Public Health England (PHE) estimate has prevented at least 6,000 deaths in the first 3 months of 2021.

There have been reports of an extremely rare adverse event of concurrent thrombosis (blood clots) and thrombocytopenia (low platelet count) following vaccination with the first dose of AstraZeneca ChAdOx1 nCoV-19 vaccine (AZD1222).

JCVI has weighed the relative balance of benefits and risks and advise that the benefits of prompt vaccination with the AstraZeneca COVID-19 vaccine far outweigh the risk of adverse events for individuals 30 years of age and over and those who have underlying health conditions which put them at higher risk of severe COVID-19 disease. JCVI

currently advises that it is preferable for adults aged <30 years without underlying health conditions that put them at higher risk of severe COVID-19 disease, to be offered an alternative COVID-19 vaccine, if available. People may make an informed choice to receive the AstraZeneca COVID-19 vaccine to receive earlier protection.

There are some adults <30 without underlying health conditions who are in phase 1, who were prioritised due to an increased risk of exposure and/or to reduce the risk of passing the infection on to vulnerable individuals. This includes health and social care workers, unpaid carers and household contacts of immunosuppressed individuals. Acting on a precautionary basis, if these persons are still unvaccinated, it is preferable for them to be offered an alternative COVID-19 vaccine, if available."

ACTIONS NOW REQUIRED

MHRA and JCVI have made clear the balance of risk is still very much in favour of vaccination. It is therefore critical that we implement their direction in a similarly balanced and operationally robust manner so that we continue to deliver our life-saving programme.

All vaccination sites should therefore take the following actions now:

Second doses

JCVI state 'all those who have received a first dose of the AstraZeneca COVID-19 vaccine should continue to be offered a second dose of AstraZeneca COVID-19 vaccine, irrespective of age.'

Therefore, for recipients in cohorts 1-9 who have received a first dose of AstraZeneca and are due to receive their second dose, no further action is required and these appointments should continue.

MHRA are clear that the only individuals who should not have a second dose of AstraZeneca are those set out below:

'Administration of the COVID-19 Vaccine AstraZeneca in patients with a history of cerebral venous sinus thrombosis, acquired or hereditary thrombophilia, heparin-induced thrombocytopenia or antiphospholipid syndrome should only be considered when the potential benefit outweighs any potential risks. Patients who have experienced major venous and arterial thrombosis occurring with thrombocytopenia following vaccination with any COVID-19 vaccine should not receive a second dose of COVID-19 Vaccine AstraZeneca.'

First doses for individuals 30 years of age and over and those who have underlying health conditions which put them at higher risk of severe COVID-19 disease

'JCVI has weighed the relative balance of benefits and risks and advise that the benefits of prompt vaccination with the AstraZeneca COVID-19 vaccine far outweigh the risk of adverse events for individuals 30 years of age and over and those who have underlying health conditions which put them at higher risk of severe COVID-19 disease.'

Therefore, for recipients in cohorts 1-9 aged 30 years and above who are scheduled to receive a first dose of AstraZeneca, vaccination should continue with consent obtained in line with the recommendations set out in the Green Book.

Adults under 30 without underlying health conditions in Phase 1

JCVI guidance states 'There are some adults <30 without underlying health conditions who are in phase 1, who were prioritised due to an increased risk of exposure and/or to reduce the risk of passing the infection on to vulnerable individuals. This includes health and social care workers, unpaid carers and household contacts of immunosuppressed individuals. Acting on a precautionary basis, if these persons are still unvaccinated, it is preferable for them to be offered an alternative COVID-19 vaccine, if available.'

For these recipients in cohorts 1-9 aged under 30 who have yet to receive a COVID-19 vaccination and are scheduled to receive a first dose of AstraZeneca on or after the 9 April, the following actions will now need to be taken:

- For those who have a first dose appointment at a vaccination centre or community pharmacy on or after 9 April, booked through the National Booking Service, these appointments will be cancelled centrally. For those booked via a local booking system, these appointments must be cancelled locally. Individuals will be asked to contact their GP team to discuss the benefit and risks to them of receiving the AstraZeneca or another vaccine.
- If, following a conversation with a clinician, an individual chooses to go ahead with the AstraZeneca vaccination, all vaccination sites should make this option available.

- If an individual chooses to have another vaccine, the NHS will put appropriate arrangements in place:
 - PCN-led Local Vaccination Services, working with system partners including Hospital Hubs, should rebook this individual in a clinic offering the Pfizer BioNTech vaccine over the coming four weeks. Guidance on how to access additional Pfizer BioNTech vaccine will follow shortly.
 - For Hospital Hubs, any available Pfizer BioNtech doses should be offered as first doses for those in cohort 1-9 aged under 30 or with contraindications.

For those who have contraindications or conditions that require special precautions

For those who have contraindications or conditions that require special precautions for use of the AstraZeneca vaccine (as listed in the updated MHRA information for UK healthcare professionals available at <https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca>), then do as follows:

- Ensure that everyone who presents for vaccination is asked about additional risk factors, using the materials provided. If they are at increased risk, they should have a discussion about the benefit and risks to them of receiving the AstraZeneca or other vaccine with a clinician.
- If, following a conversation with a clinician, an individual chooses to go ahead with the AstraZeneca vaccination, vaccination sites should make this option available.
- If an individual chooses to have another vaccine, the NHS will put appropriate arrangements in place:
 - PCN-led Local Vaccination Services, working with system partners
 - including Hospital Hubs, should rebook this group at clinics offering Pfizer BioNtech vaccines over the coming four weeks.
 - For Hospital Hubs, any available Pfizer BioNtech doses should be offered
 - as first doses for those in cohort 1-9 with the identified risk factor.
 - For those in cohorts 1-9 aged under 30 or who have an additional risk factor who have yet to receive a COVID-19 vaccination and are scheduled to receive a first dose of AstraZeneca on 8 April, it is not possible to cancel and inform individuals before their appointment.

Therefore, all sites should prepare to have individual conversations about the risks and benefits of receiving the AstraZeneca vaccine should individuals arrive for their appointment. This means all vaccination sites will need to put immediate measures in place to ensure that regulated healthcare professionals are available to support these conversations, using the [materials provided by PHE](#).

Thank you for your continued efforts and, as ever, we are hugely grateful for everything that you are doing to make the NHS-delivery of this programme the success that it is.

Yours sincerely



Dr Emily Lawson
NHS Chief Commercial
Officer and SRO



Professor Stephen Powis
National Medical Director



Dr Nikki Kanani
Medical Director for Primary
Care

JCVI statement on Use of the AstraZeneca COVID-19 Vaccine: 7 April 2021

Since the start of the pandemic over 4 million COVID-19 infections have been confirmed in the UK causing more than 120,000 deaths. Over 30 million people have received their first dose of COVID-19 vaccine since the start of the programme, which Public Health England (PHE) estimate has prevented at least 6,000 deaths in the first 3 months of 2021. Analysis of infection data since the introduction of the COVID-19 vaccines in the UK demonstrates that vaccination is highly effective and substantially reduces the risk of infection and severe COVID-19 disease.

There have been reports of an extremely rare adverse event of concurrent thrombosis (blood clots) and thrombocytopenia (low platelet count) following vaccination with the first dose of AstraZeneca ChAdOx1 nCoV-19 vaccine (AZD1222). There has been no signal for thrombosis/thrombocytopenia following receipt of other COVID-19 vaccines approved for use in the UK (Pfizer-BioNTech and Moderna). Given the very low numbers of events reported overall, there is currently a high level of uncertainty in estimates of the incidence of this extremely rare adverse event by age group. However, the available data do suggest there may be a trend for increasing incidence of this adverse event with decreasing age, with a slightly higher incidence reported in the younger adult age groups. In contrast, the risks of severe disease associated with COVID-19 increases steeply with age, with the youngest adults at lowest risk. There are currently no known risk factors for this extremely rare condition, which appears to be an idiosyncratic reaction on first exposure to the AstraZeneca COVID-19 vaccine.

Alternatives to the AstraZeneca COVID-19 vaccine currently approved for use in the UK include the Pfizer-BioNTech BNT162b2 and Moderna mRNA-1273 vaccines. JCVI has weighed the relative balance of benefits and risks and advise that the benefits of prompt vaccination with the AstraZeneca COVID-19 vaccine far outweigh the risk of adverse events for individuals 30 years of age and over and those who have underlying health conditions which put them at higher risk of severe COVID-19 disease. JCVI currently advises that it is preferable for adults aged <30 years without underlying health conditions that put them at higher risk of severe COVID-19 disease, to be offered an alternative COVID-19 vaccine, if available. People may make an informed choice to receive the AstraZeneca COVID-19 vaccine to receive earlier protection.

There are some adults <30 without underlying health conditions who are in phase 1, who were prioritised due to an increased risk of exposure and/or to reduce the risk of passing the infection on to vulnerable individuals. This includes health and social care workers, unpaid carers and household contacts of immunosuppressed individuals. Acting on a precautionary basis, if these persons are still unvaccinated, it is preferable for them to be offered an

alternative COVID-19 vaccine, if available. JCVI is currently finalising its advice on phase 2 of the programme, particularly for healthy people under 30 years of age, and this will be published in due course.

To date, there are no reports of the extremely rare thrombosis/thrombocytopenia events following receipt of the second dose of the AstraZeneca COVID-19 vaccine. All those who have received a first dose of the AstraZeneca COVID-19 vaccine should continue to be offered a second dose of AstraZeneca COVID-19 vaccine, irrespective of age. The second dose will be important for longer lasting protection against COVID-19.

JCVI advises that all individuals offered a COVID-19 vaccine should be fully informed about the benefits and risks of vaccination. This should include clear information on the extremely rare thrombosis/thrombocytopenia adverse event, how to monitor for symptoms that might be related to the adverse event, and what action should be taken by individuals and health professionals in the event of such symptoms arising. PHE is preparing updated information for those being offered COVID-19 vaccines, and for health professionals, which will be available through the GOV.UK website.

Read the full statement online [here](#).

Press Release : MHRA Issues New Advice, Concluding a Possible Link Between COVID-19 Vaccine AstraZeneca and Extremely Rare, Unlikely to Occur Blood Clots

Read the full press release [here](#)

The benefits of vaccination continue to outweigh any risks but the MHRA advises careful consideration be given to people who are at higher risk of specific types of blood clots because of their medical condition.

- The MHRA is not recommending age restrictions in COVID-19 Vaccine AstraZeneca vaccine use.
- The MHRA's scientific review of UK reports of extremely rare and unlikely to occur specific blood clots with lowered platelets has concluded that the evidence of a link with COVID-19 Vaccine AstraZeneca is stronger but more work is still needed.
- By 31 March 20.2 million doses of the COVID-19 Vaccine AstraZeneca had been given in the UK meaning the overall risk of these blood clots is approximately 4 people in a million who receive the vaccine.
- Anyone who did not have these side effects should come forward for their second dose when invited.
- The data suggest there is a slightly higher incidence reported in the younger adult age groups and the MHRA advises that this evolving evidence should be taken into account when considering the use of the vaccine.
- The MHRA is now issuing updated guidance for healthcare professionals on how to minimise risks, as well as further advice on symptoms for vaccine recipients to look out for 4 or more days after vaccination.
- 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.

The Joint Committee on Vaccination and Immunisation (JCVI) have also published [a statement](#) following reports of an extremely rare adverse event after vaccination with the first dose of the AstraZeneca COVID-19 vaccine.

This includes information on the use of the vaccine in those under 30.

[Updated information is being provided for people and healthcare professionals](#) on the possible risk of extremely rare and unlikely to occur specific types of blood clots following vaccination with the COVID-19 Vaccine AstraZeneca, the Medicines and Healthcare products Regulatory Agency (MHRA) said today.

The MHRA has undertaken a thorough review into UK reports of a very 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.

These reports have 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, which includes lay representatives and advice from leading haematologists.

Up to and including 31 March 2021, the MHRA had received 79 UK reports of blood clotting cases alongside low levels of platelets following the use of the COVID-19 Vaccine AstraZeneca:

- 44 of the 79 cases were of CVST with thrombocytopenia
- 35 of the 79 cases were of thrombosis in other major veins with thrombocytopenia
- 79 cases occurred in 51 women and 28 men, aged from 18 to 79 years. It should be noted that more women have been vaccinated with COVID-19 Vaccine AstraZeneca than men.
- Sadly, 19 people have died out of the 79 cases – 13 females and 6 males. 11 out of the 19 people who died were under the age of 50, 3 of whom were under 30. 14 of these 19 cases were of CVST with thrombocytopenia and 5 were of thrombosis with thrombocytopenia.
- All 79 cases occurred after a first dose of the vaccine.

This risk, based on reports up to and including 31 March, is slightly higher than the risk calculated from the reports published up to and including 24 March. However, likelihood of these blood clots occurring is still extremely rare.

As a precaution, administration of COVID-19 Vaccine AstraZeneca in people of any age who are at higher risk of blood clots because of their medical condition should be considered only if benefits from the protection from COVID-19 infection outweighs potential risks.

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.

Pregnancy predisposes to thrombosis, therefore women should discuss with their healthcare professional whether the benefits of having the vaccine outweigh the risks for them.

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.

It is important to note that this type of blood clot together with lowered platelets can rarely occur naturally in unvaccinated people as well as in people with COVID-19 disease.

While the MHRA continues to investigate these cases, as a precautionary measure anyone that develops symptoms after vaccination is advised to seek prompt medical advice, such as:

- shortness of breath, chest or persistent abdominal pain, leg swelling
- blurred vision, confusion or seizures
- unexplained pin-prick rash or bruising beyond the injection site

Furthermore, anybody with new onset of severe or persistent headache that does not respond to simple painkillers starting four days or more after vaccination should speak to their doctor.

Dr June Raine, MHRA Chief Executive, said:

Over 37 million doses of vaccines against COVID-19 have now been administered in the UK, saving thousands of lives through the biggest vaccination programme that has ever taken place in the UK.

No effective medicine or vaccine is without risk. We continually monitor safety during widespread use of any vaccine. This is to ensure vaccines are performing as expected, to identify any new side effects that may arise, and to ensure the benefits continue to outweigh the risks.

The public's safety is always at the forefront of our minds and we take every report of a suspected side effect very seriously indeed. We thoroughly analyse each and every report as we receive it and although the number of reports of CVST and other thromboembolic events has increased over the last week, so has the overall number of vaccinations administered, therefore these blood clots remain extremely rare and unlikely to occur.

We ask anyone who suspects they have experienced a side effect linked with their COVID-19 vaccine to report it to the [Coronavirus Yellow Card website](#). It is still vitally important that people come forward for their vaccination when invited to do so.

Professor Sir Munir Pirmohamed, Chair of the Commission on Human Medicines, said:

The independent [Commission on Human Medicines \(CHM\)](#) and its COVID-19 Expert Working Group, together with leading haematologists, has conducted a rigorous scientific analysis of all available evidence regarding reports of thromboembolic events occurring together with low platelets and COVID-19 Vaccine AstraZeneca and usage of the vaccine in different age groups.

We have a rich source of data – the best data there is – and the MHRA and CHM will continue to keep this under close observation. The public deserve nothing less.

Slides from press conference

[Slides from 7 April 2021 press briefing - Communicating the potential benefits and harms of the Astra-Zeneca COVID-19 vaccine](#) (PDF, 360KB, 5 pages)

Notes to editor

- Up to and including 31 March we have received 2 reports of blood clots (thromboembolism) reported with thrombocytopenia for the Pfizer/BioNTech vaccine. By this date, approximately 11 million first doses and 3.5 million second doses had been given.
- The Expert Haematology Panel has issued [guidance on thrombosis and thrombocytopenia possibly occurring after vaccination with COVID-19 vaccines](#). This includes information on presentation and typical laboratory features, and treatment recommendations. The guidance also includes advice on recommended investigations for possible cases.
- The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
- The Medicines and Healthcare products Regulatory Agency ('the agency') has three centres. The MHRA, the [National Institute for Biological Standards and Control \(NIBSC\)](#) and the [Clinical Practice Research Datalink \(CPRD\)](#). The agency is an executive agency of the Department of Health and Social Care.
- The [Commission on Human Medicines](#) is the UK Government's independent advisory body. It advises ministers on the safety, efficacy and quality of medicinal products.
- The [COVID-19 Vaccines Benefit Risk Expert Working Group](#) of the Commission on Human Medicines is formed from 27 experts from outside of the MHRA, including virologists, epidemiologists, immunologists and toxicologists.
- The MHRA encourages anyone to report any suspicion or concern they have beyond the known, mild side effects on the [Coronavirus Yellow Card site](#). Reporters do not need to be sure of a link between a vaccine and a suspected side effect but are still encouraged to report.
- For more information on COVID-19 vaccine adverse reactions, see the MHRA's [weekly report](#)
- For more information on COVID-19 Vaccine AstraZeneca, see the MHRA's [regulatory approval decision page](#)

Reminder of Guidance on: COVID-19 Vaccination of Patients Aged Less Than 18 Years Old

All vaccination locations are strongly reminded that people under 18 should not be vaccinated with the Astra-Zeneca (AZ) COVID-19 vaccine, unless there are extenuating circumstances. Only the Pfizer vaccine is authorised for use in people aged 16-17 years. However, in certain exceptional circumstances it is appropriate to use AZ for this age group instead. These include:

- People with severe allergies/anaphylaxis to Pfizer or its components;
- People who are housebound (where it can be difficult to transport Pfizer); and
- When all efforts to enable the individual to receive Pfizer at another time and/or another location have been exhausted.

See the Green Book (chapter 14a) for further details including indications for the 12-16 year age group.

It is not appropriate to give AZ to people under 18 years unless in the specific exceptional circumstances outlined above.

Further, it is unlawful to vaccinate someone under 18 years with AZ unless delivered directly by an Authorised Prescriber (usually a doctor) or under a Patient Specific Direction (PSD) which has also been completed by an Authorised Prescriber. Completing a PSD involves assessing the patient's individual circumstances, obtaining informed consent (including a discussion about the risks and benefits of using an unauthorised vaccine), and documenting this accordingly on a paper or electronic PSD that is attached to the patient's record. Click [here](#) to see more information about the requirements for a PSD.

All vaccination locations are to check that they have suitable systems in place to ensure that:

People under 18 years are actively identified when they make a booking and are only allocated to sessions where the Pfizer vaccine is available.

They are identified when they arrive on site and directed appropriately so that their eligibility for AZ is fully assessed and a PSD completed when needed.

There are proper checks and balances built into the vaccination process from start-to-finish to ensure they subsequently receive the correct vaccine, and that this is fully documented.

All instances where someone receives AZ without a signed PSD in place are promptly reported to their RVOC and fully investigated.

Further guidance will be shared in the near future.

Reminder of Guidance on: Vaccination Site SOP – Maternity Escalation Protocol

To ensure that women who are or may be pregnant can provide informed consent for vaccination, the vaccine site must have the following provisions in place:

A health care professional who is able to discuss the potential benefits and risks of COVID-19 vaccination in pregnancy and gain informed consent using the vaccinator checklist.

For women with further queries that could be resolved on site: a pathway for obtaining advice from the on-site 'Clinical Lead', for women to be able to make their decision during their appointment.

For women who, after vaccination counselling on-site, would prefer to have a further conversation with an experienced GP or health care professional from the maternity service: a pathway to obtain this in a timely manner, ideally within 3-5 working days, which may include either the woman or the health professional organising this through the vaccination site's identified point of contact within the site or with local GP/maternity services. Alternatively, it may be arranged using contact details a woman has been given for her own GP/maternity service where this is not local.

Please also see link to [Pregnancy and vaccination actions](#).

Reminder of Guidance on: Shared Learning - Denying Access to Treatment/Intervention

As we vaccinate the younger groups of patients, it may be the case that parents bring dependent children to their vaccination appointment.

Colleagues are reminded that reasonable adjustments can be made for people in such circumstances, and every effort should be made to ensure that individuals can receive their vaccine at their stated appointment time.

Ultimately, the senior clinician on duty has the responsibility for patient safety and it is important that they are informed of any concerns that other colleagues may have about an individual, so that they can make a risk assessment at the time and that any necessary adjustments can be made.

Denying treatment/intervention, for any reason, is a clinical decision and it must be made by the most senior clinician on duty at the time. They will be able to assess the risks and make a clinical decision which will then be documented. All staff need to be aware of the need to escalate these situations to the senior clinician.

In the meantime, as a way of preparing for the younger cohorts, we are looking at ways of strengthening the guidance for parents at the point of booking. Patients booked in for vaccination are currently asked to attend on their own where possible to minimise the risk of COVID-19 infection. However, any individual is allowed to attend with another person, particularly if they need support, for example if they are in a wheelchair, are frail or have a learning disability. Parents with young babies or children need not be turned away, unless following a risk assessment by the senior clinician. They do need to be supported to receive the vaccine. As the cohorts move to younger populations, it is more likely that adjustments will need to be made to ensure no one is disadvantaged because they have dependents with them.

Reminder of Guidance on: Second Dose Vaccination

Colleagues delivering second doses of the COVID-19 vaccine should ascertain evidence of the type of vaccine administered for the first dose, rather than relying on the individual to confirm these details. In all cases, this should be done by first checking the patient's digital records or the vaccination card that was issued to the patient after their first dose, before vaccinating with the second dose.

Vaccination events should always be recorded digitally where possible, and paper recording should only be used in very limited, exceptional circumstances where digital recording is not available.

For further information please see [2nd Dose FAQs](#) (NHS Futures)

Supporting COVID-19 Vaccine Uptake During Ramadan

The Islamic holy month of Ramadan is an important time for practising Muslims that involves a month of fasting, worship and community celebration. It is due to begin on 12 April 2021 (subject to moon sightings) bringing with it a change to normal daily life for many of our Muslim communities and NHS workforce.

Why Ramadan may impact on vaccine uptake

Scholarly leaders and the British Islamic Medical Association have stated that it is permissible to receive the COVID-19 vaccine while fasting during Ramadan. Many Muslims may be wary of the medical impact of having a vaccination whilst fasting such as the potential side effects including nausea, dizziness and vomiting on the day or following day of vaccination which could lead to them having to break or forgo their fast. They may also have a preference to be vaccinated after Ramadan.

To help build confidence, reduce any barriers to access and support the uptake of the COVID-19 vaccine amongst Muslim communities during the month of Ramadan, it is vital that system partners consider how they will reach out and engage with communities during this time.

Please find attached a COVID-19 Vaccine Deployment Programme – Ramadan Guide and Supporting COVID-19 Vaccine Uptake During Ramadan Guide.

Use of Sedation for Those with Learning Difficulties.

The use of sedation for vaccination for those with a learning disability has been discussed by the regional Clinical Reference Group. There is consensus that this should be managed on an individual best interest basis by clinicians and carers, who are aware of the individual's needs and what action would be taken in other circumstances where the person required medical treatment.

Sedation should be considered only after other options have been fully explored. The type of sedation should be based on the clinicians knowledge of the individual's circumstances and medical history, and should be the minimum possible to enable the procedure to be completed in line with the best interest and risk assessments undertaken.

All COVID-19 vaccination queries and incidents should be directed to:
england.swcovid19-voc@nhs.net