

Regional Clinical Advice Response Service 23/04/21

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. [JCVI Announcement Regarding COVID-19 Vaccination During Pregnancy and Next Steps](#)
2. [Summary of changes within the Green Book](#)
3. [AstraZeneca COVID-19 Vaccine Contraindications](#)
4. [Moderna Vaccine National Protocol and PGD](#)
5. [Black Particles in Pfizer Post-Dilution](#)
6. [Blunt needles identified](#)
7. [Patients Without an NHS Number](#)
8. [COVID-19 vaccine animations launched to help tackle disinformation](#)
9. [Case Study: Newham Vaccination Outreach Service](#)

JCVI Announcement Regarding COVID-19 Vaccination During Pregnancy and Next Steps

Read the full letter online [here](#)

Dear colleague

We are writing to you following the update from the Joint Committee on Vaccination and Immunisation (JCVI) in relation to COVID-19 vaccination during pregnancy and actions to take. The update has been published and can be found here: [JCVI issues new advice on COVID-19 vaccination for pregnant women - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/news/jcvi-issues-new-advice-on-covid-19-vaccination-for-pregnant-women)

NHS England and NHS Improvement



The statement from JCVI states:

“There have been no specific safety concerns identified with any brand of coronavirus (COVID-19) vaccines in relation to pregnancy.

[Real-world data from the United States](#) shows that around 90,000 pregnant women have been vaccinated, mainly with mRNA vaccines including Pfizer-BioNTech and Moderna, without any safety concerns being raised.

Based on this data, the Joint Committee on Vaccination and Immunisation (JCVI) advises that it's preferable for pregnant women in the UK to be offered the PfizerBioNTech or Moderna vaccines where available. There is no evidence to suggest that other vaccines are unsafe for pregnant women, but more research is needed.

The advice, published in Public Health England's [Green Book](#), a clinical professional guide for vaccinators in the UK, still advises that pregnant women should discuss the risks and benefits of vaccination with their clinician, including the latest evidence on safety and which vaccines they should receive.”

Public Health England's Green Book has been updated to reflect this latest advice from the JCVI advice and can be found [here](#).

Actions Now Required

First doses

Pregnant woman in eligible cohorts who have yet to receive a COVID-19 vaccination, should be offered the Pfizer-BioNtech vaccine or Moderna vaccine. This currently includes women who are pregnant in cohorts 1, 2, 4, 6 and the 45-49 year old age group. This means that all vaccination sites who are offering the Moderna or Pfizer BioNtech vaccine are required to ensure that from 19 April 2021, pregnant women are able to book appointments for their vaccination at the same time as non-pregnant women, based on age and clinical group.

The National Booking System (NBS) has been updated to recommend that those who are pregnant speak to a healthcare professional such as an obstetrician, midwife or GP team before booking their first dose appointment. Further updates are planned to the NBS over the coming days to support eligible pregnant women to book an appropriate appointment. We will share further details on this in due course. Those using local booking systems will need to update their systems and processes to reflect the JCVI revised advice.

All vaccination sites should implement screening procedures to ensure pregnant women are identified and offered the Pfizer BioNtech or Moderna vaccine.

For sites that do not currently offer an alternative vaccine to the AstraZeneca vaccine, they should cancel first dose appointments if they know the patient is pregnant and direct patients to a PCN site or a vaccination centre that is administering the Pfizer-BioNTech or Moderna vaccine. Pregnant women already booked for a first dose at a community pharmacy-led site or a vaccination centre will not have their appointments automatically cancelled.

Healthcare professionals should discuss the risks and benefits of vaccination with each pregnant woman presenting for vaccination, as part of the pre-vaccination clinical assessment and consent process. Guidance is contained within Chapter 14a of the Green Book. Patients should be supported to ask questions or seek further information and where necessary, the person should be redirected to an obstetrician, midwife or GP team for further advice and guidance.

JCVI have also stated that “Woman who are planning pregnancy, are in the immediate postpartum, or are breastfeeding can be vaccinated with any vaccine, depending on their age and clinical risk group.” PHE’s Green Book advises that “There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that breastfeeding women may be offered any suitable COVID-19 vaccine. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for immunisation against COVID-19; at the same time, women should be informed about the absence of full safety data for the vaccine in breastfeeding.”

Second doses

PHE’s Green Book advises that ‘Pfizer and Moderna vaccines are the preferred vaccines for pregnant women of any age, because of more extensive experience of their use in pregnancy. Pregnant women who commenced vaccination with AstraZeneca, however, are advised to complete with the same vaccine’.

‘If a woman finds out she is pregnant after she has started a course of vaccine, she may complete vaccination during pregnancy using the same vaccine product (unless contra-indicated). Alternatively, vaccination should be offered as soon as possible after pregnancy.’

Therefore, for pregnant women who have received a first dose of AstraZeneca and are due to receive their second dose, no further action is required and second dose appointments should continue as planned.

Vaccine supply

PCN-led and Hospital Hub sites should first look to vaccinate eligible pregnant women with Pfizer-BioNTech through excess supply for second dose clinics.

PCNs should escalate via their Regional Vaccination Operations Centre (RVOC) if they have insufficient Pfizer vaccine to vaccinate their eligible patients who are pregnant, as per the guidance shared with PCN sites last week. Local systems will have a key role to play in managing demand and ensuring patients have access to the appropriate vaccines.

If Hospital Hubs have insufficient Pfizer-BioNTech supply to vaccinate an eligible pregnant woman, they should direct the patient to a PCN-led site or a Vaccination Centre offering the Moderna vaccine.

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 Nikki Kanani
Medical Director for Primary Care



Dr Jonathan Leach OBE
NHS England Medical Director
for COVID-19 Immunisation

Summary of changes within the Green Book

The Chapter 14a of the “Green Book” regarding COVID-19 – SARS-COV-2 is updated on a regular basis as new vaccines become available, knowledge increases and following feedback.

The most recent version dated 13 Apr 21, contains some significant amendments which should be brought to the attention of clinical and administrative staff involved with the deployment of COVID-19 vaccination.

[COVID-19: The green book, Chapter 14a.](#)

A summary of the significant changes are available for reference [here](#) and below:

Vaccine effectiveness

Real world data on effectiveness (page 7).

“Vaccine effectiveness data from the UK is now emerging. A single dose of either the Pfizer or the AstraZeneca vaccines has been shown to provide around 60% protection against symptomatic disease; vaccinated cases are also around 40% less likely to require hospital admission or to die”.

Safety

Updated information regarding safety (page 7).

Further information is provided on the safety profile of the Pfizer, Moderna and Astra Zeneca vaccines. There is inclusion of emerging information regarding thromboembolic events as follows:

“Recently, a rare condition involving serious thromboembolic events accompanied by thrombocytopaenia, has been reported after AstraZeneca vaccination. The condition presents with unusual venous thrombosis, including cerebral venous sinus thrombosis, portal vein thrombosis, and sometimes arterial thrombosis, with low platelet count and high D-dimer measurements. The condition has similarities to heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2) and patients usually have positive antibody to platelet factor 4. The majority of the events occurred between 5 and 16 days following vaccination. (Greinacher et al, 2021). The reported rate of this event in the UK is around 4 per million, although a higher incidence appears to be seen in younger individuals. Overall, JCVI, MHRA and the WHO remain clear that the benefits of vaccination outweigh this small risk for adults aged 30 years and over, adults who are clinically extremely vulnerable and those with underlying clinical risks as defined in table 3”.

Dosage interval

Clarification of dosage interval for the Astra Zeneca vaccine (page 9). To note, UK policy remains that the 2nd dose should not be offered before 77 days, unless there are specific reasons.

“Based on good evidence of higher clinical protection, JCVI currently recommend that, ideally, an eight week minimum interval should be observed for this vaccine. An interval of 28 days may be observed when rapid protection is required (for example for those about to receive immunosuppressive treatment)”.

Vaccinating specific cohorts

- Inclusion for vaccination of the adult contacts of people who are immunosuppressed and also adult carers (page 13).
- Advice on the vaccination of citizens aged between ages 40-49, 30-39 and 18-29 (page 15).
- Advice on the vaccination of healthy adults aged 18-30 years (page 15).

“Evidence suggests that risk of serious COVID-19 disease is strongly related to age, and risk of COVID-19 mortality, hospitalisation and ICU admission is lower in younger adults. Based on current evidence JCVI are advising a preference for a vaccine other than AstraZeneca to be offered to healthy people under 30 years of age, including health and social care workers, unpaid carers and household contacts of immunosuppressed individuals. In the absence of a suitable alternative these individuals may defer or choose to receive the AstraZeneca vaccine provided they have been informed and understand the relative risks and benefits. Those who have already received a dose of AstraZeneca vaccine should complete with the same vaccine (see contraindications and precautions)”.

Vaccinating pregnant women

Advice on vaccine choice for pregnant women of any age (pages 16 and 17). “Pfizer and Moderna vaccines are the preferred vaccines for pregnant women of any age, because of more extensive experience of their use in pregnancy. Pregnant women who commenced vaccination with AstraZeneca, however, are advised to complete with the same vaccine”.

2nd dose of AZ Vaccine

Guidance on 2nd dose of Astra Zeneca in patients who experience an episode of thrombosis with thrombocytopaenia after the first dose (page 16).

“Individuals who have received a first dose of the AstraZeneca vaccine should complete the course with the same vaccine, with the exception of those who experience an episode of thrombosis combined with thrombocytopaenia (see contraindications and precautions)”.

Blood clots after COVID-19 vaccination

Information on thrombosis and thrombocytopaenia occurring after COVID-19 vaccination (page 22).

“There is no evidence of any underlying risk factors in the individuals affected by this condition who have mainly been previously healthy. The condition is rare, tends to present with unusual forms of clotting and the mechanism is believed to be an idiosyncratic reaction related to an immune response to the AstraZeneca vaccine. This may be related to the recipient’s polymorphisms in genes encoding Fc receptors in the immune system and is an area of active research. Because of this likely immune mechanism, there is no reason to believe that individuals with a past history of clots or of certain thrombophilic conditions would be at increased risk of this very rare condition. Similarly, although pregnancy increases the risk of clotting conditions, there is no evidence that pregnant women, those in the post-COVID-19 - SARS-Cov-2 partum or women on the contraceptive pill are at higher risk of the specific condition of thrombosis in combination with thrombocytopaenia after the AstraZeneca vaccine. There have been no confirmed cases reported in pregnant women to date.

The contra-indications to vaccination with the AstraZeneca COVID-19 vaccine have now been amended to include individuals who have a history of a previous episode of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2). These individuals may be offered vaccination an alternative COVID-19 vaccine.

Individuals who experience a clotting episode with concomitant thrombocytopaenia following the first dose of AstraZeneca vaccine should be properly assessed. If they are considered to have the reported condition, further vaccination should be deferred until their clotting has completely stabilised, and they should then be considered for a second dose of an alternative product. Based on the analogy of HITT, antibody to platelet may persist for around six months.

Individuals who have received the first dose of AstraZeneca vaccine without developing this rare condition are advised to receive the second dose of the same vaccine at the currently recommended interval of around 12 weeks”

AstraZeneca COVID-19 Vaccine Contraindications

The MHRA on Thursday updated the [contraindications](#) for the COVID-19 Vaccine AstraZeneca. These are now:

*Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Patients with a history of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2).*

Patients who have experienced major venous and/or arterial thrombosis occurring with thrombocytopenia following vaccination with any COVID-19 vaccine should not receive a second dose of COVID-19 Vaccine AstraZeneca.

Please note that this condition is rare, tends to present with unusual forms of clotting and the mechanism is believed to be an idiosyncratic reaction related to an immune response to the first dose of the COVID-19 Vaccine AstraZeneca.

Because of this likely immune mechanism, there is no reason to believe that individuals with a past history of clots or of certain thrombophilic conditions would be at increased risk of this very rare condition.

As a precautionary measure, administration of the COVID-19 Vaccine AstraZeneca in patients with a history of cerebral venous sinus thrombosis, or antiphospholipid syndrome should only be considered when the benefit outweighs any potential risks.

Further information can be found in the [updated chapter of the green book](#).

Frequently Asked Questions: MHRA and JCVI guidance on COVID-19 Vaccine AstraZeneca and very rare clotting disorders are available [here](#).

Further information for healthcare professionals is also available [here](#).

Moderna Vaccine National Protocol and PGD

Colleagues will have seen that the Moderna COVID-19 Vaccine has been launched in specific Vaccination Centres.

The National Protocol for Moderna is available here:

<https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/legal-mechanisms/national-protocols-for-covid-19-vaccines/>

The PGD is available here: <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/legal-mechanisms/patient-group-directions-pgds-for-covid-19-vaccines/>

A template for a PSD is also available on NHS Future [here](#).

Black Particles in Pfizer Post-Dilution

There have been some reported issues regarding black particles being seen post-dilution with the Pfizer COVID-19 vaccine. DMRC have confirmed that no batch issues have been identified at present, but they are aware of the reports of black particles which is likely related to coring of the bung, and Pfizer are now putting in place corrective procedures to try and minimise this occurring with the product.

Please continue to report these or similar events to MHRA DMRC as they are keeping in close contact with the company regarding these issues.

DMRC contact details:

Email: DMRC@mhra.gov.uk

Yellow Card <https://yellowcard.mhra.gov.uk/>

Blunt needles identified

We have been made aware that some areas have identified blunt needles within their supplies. PHE are working with the manufacturer and is meeting with them twice daily to work out a plan of action for sites/regions with affected stock. We are not aware of any affected needles in the South West. If providers identify any blunt needles, then affected stock should be quarantined and sites should follow the following process:

- Yellow card to MHRA
- Notify NVOC via the SVOC/RVOC route
- Notify COVID19PHEsupplies@phe.gov.uk

Patients Without an NHS Number

The tech solution for recording patients with no NHS number is now live. It enables all sites to record in the Covid vaccination IT system (Pinnacle) the vaccination of a patient without an NHS number, meaning that payment can easily flow.

After a site has entered vaccination event for a patient without an NHS number, behind the scenes, work will take place to try to match the patient to an existing NHS number attached to that patient, using the demographic details they supply at the point of vaccination.

If an NHS number already exists for them (which may still be found, even if it could not be found by the patient or vaccinator using the Patient Demographic Service look up in Pinnacle or the tool on the NHS website). Where an NHS number can definitely not be found, one will be assigned to the patient. Either way, there will be no further action for the the vaccination site. Previous paper-based or locally kept records for patients without an NHS number can also now be uploaded, and payment therefore claimed for these vaccinations too.

A solution for what to do about patients who don't want any kind of local or national digital record is currently being worked on.

COVID-19 vaccine animations launched to help tackle disinformation

NHS England and NHS Improvement has launched a series of animations aimed at tackling disinformation about the COVID-19 vaccine. Aimed specifically at encouraging uptake in ethnic minority groups, the animations are available in 17 different languages and are suitable for use on a wide range of social media platforms.

They cover key topics including vaccine safety, how it was tested, how it was developed so quickly, what is in it, and what the side effects are.

Original files can be downloaded from the campaign resource centre in the form of [short clips](#) and also a [longer video](#), and the English versions are also available on [YouTube](#).

Case Study: Newham Vaccination Outreach Service

Read how Barts Health NHS Trust has worked with local community groups to achieve success in vaccinating their diverse population through outreach work delivered by the large-scale NHS COVID-19 Vaccination Centre Newham at ExCel London, [here](#).

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