

Clinical information for vaccine consenters: AstraZeneca vaccine

DISCLAIMER: Information within this document may be updated before the PGD or Protocol you are working under. In the event of a discrepancy, always adhere to your PGD/Protocol.

This document is regularly updated; please download the most recent version:

https://www.ncl-mon.nhs.uk/wp-content/uploads/Guidelines/0_AstraZeneca_Information_for_vaccinators.pdf



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Key references

- [AstraZeneca vaccine: Information for Healthcare Professionals](#) (similar to an SPC)
- [Specialist Pharmacy Service: Answers to Questions specific to AstraZeneca vaccine](#)
- [Immunisation against infectious disease: Chapter 14a – COVID-19](#) (The Greenbook)
- [COVID-19 vaccination programme: Information for healthcare practitioners](#)

1 Administration & dosing

<p>1.1 Timing of the second dose</p>	<p>Second dose will be given between 4 and 12 weeks after the first dose as recommended by the JCVI¹, and most likely towards the end of that window ^a.</p> <p>This interval has been shown to be effective and maximises the rate at which people can be protected:</p> <ul style="list-style-type: none"> • Trial data showed substantial protection (73%) is achieved 22 days after one dose of the AstraZeneca vaccine ^b • Real-world data, from healthcare workers, shows no decline in protection between first and second doses ^c • The second dose is required for long-term protection ^a <p>Based on good evidence of higher clinical protection, 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.¹</p> <p>^a https://www.gov.uk/government/news/statement-from-the-uk-chief-medical-officers-on-the-prioritisation-of-first-doses-of-covid-19-vaccines (30 December 2020)</p> <p>^b JCVI statement https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103132 (31 December 2020)</p> <p>^c PHE monitoring of the early impact and effectiveness of COVID-19 vaccination in England (March 2021) https://www.gov.uk/government/publications/phe-monitoring-of-the-effectiveness-of-covid-19-vaccination</p>
<p>1.2 Gap between doses was too long</p>	<p>See 'Interval between doses is longer than recommended'</p> <p>https://www.sps.nhs.uk/articles/dosing-information-for-astrazeneca-covid-19-vaccine/</p>
<p>1.3 Gap between doses was too short</p>	<p>See 'Interval between doses is less than recommended'</p> <p>https://www.sps.nhs.uk/articles/dosing-information-for-astrazeneca-covid-19-vaccine/</p>
<p>1.4 Different brand for second dose</p>	<p>See 'The same brand of vaccine is unavailable for the second dose'</p> <p>https://www.sps.nhs.uk/articles/dosing-information-for-astrazeneca-covid-19-vaccine/</p>

<p>1.5 Overseas vaccinations</p>	<p>See 'Individuals who received COVID vaccination overseas' (pg 13) and Appendix 1 https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners²</p> <p>Patients should be asked to contact their GP surgery so that their overseas vaccinations can be recorded on their healthcare record.</p>
<p>1.6 Guidance for children and young people</p>	<p>16-18 years:</p> <ul style="list-style-type: none"> • Eligibility criteria: 'Clinically extremely vulnerable' and 'At risk' (JCVI Priority Group 4 and 6 respectively)¹ • Preferred vaccine: Pfizer¹ • Legal administration mechanism: PSD, PGD or National Protocol^a • Alternative vaccine: Moderna (off-label) can be offered¹ via PSD unless otherwise contraindicated. Young people who have had a first dose of AstraZeneca vaccine, however, should complete with the same vaccine¹. <p>12-16 years:</p> <ul style="list-style-type: none"> • Eligibility criteria: Severe neuro-disabilities <i>and</i> who tend to get recurrent respiratory tract infections <i>and</i> who frequently spend time in specialised residential care settings. RCGP indicates that GPs should seek advice from the patient's paediatrician prior to administration.^a • Preferred vaccine: Pfizer (off-label)¹ • Legal administration mechanism: PSD • Alternative vaccine: Moderna (off-label) can be offered¹ via PSD unless otherwise contraindicated. Young people who have had a first dose of AstraZeneca vaccine, however, should complete with the same vaccine¹. <p><12 years:</p> <ul style="list-style-type: none"> • Eligibility criteria: Nil¹ <p>^a NHSE/I. Publication approval reference: C1124. Vaccination of JCVI cohorts 5-6 and additional funding for vaccination in residential settings (13 February 2021)</p>

1.7 Vaccine administration error	<p>See 'Inadvertent vaccine administration errors' https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners</p> <p>This provides advice for inadvertent administration of:</p> <ul style="list-style-type: none">• The whole multi-dose vial• Over-diluted vaccine• Incomplete dose of vaccine• Vaccine which was subject to storage or preparation error
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2 History of allergy or anaphylaxis

2.1	History of allergy (inc. anaphylaxis) before first dose	Follow North Central London flow diagram – Page 1 https://www.ncl-mon.nhs.uk/wp-content/uploads/Guidelines/0_Managing_Allergy_COVID-19_vaccine.pdf
2.2	Allergy to first dose of COVID-19 vaccine	Follow North Central London flow diagram – Page 2 https://www.ncl-mon.nhs.uk/wp-content/uploads/Guidelines/0_Managing_Allergy_COVID-19_vaccine.pdf
2.3	Allergy – latex	The vaccine can be considered not to contain latex and poses the same minimal risk as other injectable medicines presented in vials with a bromobutyl rubber stopper ^a ^a https://www.sps.nhs.uk/articles/advising-individuals-with-allergies-on-their-suitability-for-astrazeneca-covid-19-vaccine/ (24 March 2021)
2.4	Allergy – thiomersal or mercury	This vaccine does not contain any preservatives, thiomersal or any mercury derived product. ^a ^a https://www.sps.nhs.uk/articles/advising-individuals-with-allergies-on-their-suitability-for-astrazeneca-covid-19-vaccine/ (24 March 2021)
2.5	Allergy – food	See ‘Foods’ (covers egg, gelatin, gluten, peanut or tree nut derivatives & soy) https://www.sps.nhs.uk/articles/advising-individuals-with-allergies-on-their-suitability-for-astrazeneca-covid-19-vaccine/

3 Cautions and contraindications

<p>3.1 Thrombotic disorders</p>	<p>The following patient should not receive AstraZeneca: ³</p> <ul style="list-style-type: none"> • 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 (known as vaccine induced thrombosis with thrombocytopenia; VITT) should not receive a second dose of COVID-19 Vaccine AstraZeneca. <p>Otherwise, the Green Book states: ¹</p> <ul style="list-style-type: none"> • 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 [VITT]. • Although pregnancy increases the risk of clotting conditions, there is no evidence that pregnant women, those in the post-partum period or women on the contraceptive pill are at higher risk of [VITT]. • Individuals who have received the first dose of AstraZeneca vaccine without developing [VITT] are advised to receive the second dose of the same vaccine. <p>NHSE/I (London) COVID-19 Clinical Advice Response Service (CARS) have advised Green Book advice should be followed.</p>
<p>3.2 Thrombophilia</p>	<p>This includes including factor V Leiden, protein C deficiency, protein S deficiency, antithrombin deficiency, antiphospholipid syndrome:</p> <ul style="list-style-type: none"> • Patient anticoagulated: See 'Cautions and contraindications: Taking anticoagulation or bleeding disorders' • Not anticoagulated: No additional measures required <p>Thrombophilia is not a precaution for the AstraZeneca vaccine. ^{1,3}</p>
<p>3.3 Bleeding disorders</p>	<p>See 'Use in patients with bleeding disorders' https://www.sps.nhs.uk/articles/using-covid-19-vaccines-in-patients-with-anticoagulation-and-bleeding-disorders/</p>

<p>3.4 Taking anticoagulation</p>	<p>DOACs, heparin or fondaparinux</p> <ul style="list-style-type: none"> • Individuals receiving direct oral anticoagulant (apixaban, dabigatran, edoxaban & rivaroxaban), full dose heparin (inc. low-molecular weight heparin) or fondaparinux injections can all receive the COVID-19 vaccine. • A fine needle (23 or 25 gauge) should be used for vaccination, followed by firm pressure applied to the site without rubbing for at least 2 minutes. <p>Warfarin</p> <ul style="list-style-type: none"> • Individuals receiving warfarin whose INR tests are up-to-date and whose latest INR is below <4.0 can receive the COVID-19 vaccine. Individuals who are overdue their INR test or have supra therapeutic INR should wait until their INR is confirmed as being <4.0. • A fine needle (23 or 25 gauge) should be used for vaccination, followed by firm pressure applied to the site without rubbing for between 2 and 5 minutes depending on the INR (or as long as need be to ensure no on-going bleeding). • If there is any doubt about the level of anticoagulation control, the clinician responsible for prescribing and monitoring the patient's anticoagulant treatment should be consulted. <p>^a https://www.sps.nhs.uk/articles/using-covid-19-vaccines-in-patients-with-anticoagulation-and-bleeding-disorders/ (7 January 2021)</p> <p>^b London Region (NHS E & I) Position Statement: Covid 19 vaccine and patients prescribed anticoagulants (8th December 2020)</p>
<p>3.5 Acute illness (other than COVID-19 infection)</p>	<p>Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. ¹</p> <p>If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness (including COVID-19) by wrongly attributing any signs or symptoms to the adverse effects of the vaccine.¹</p>
<p>3.6 Current or previous COVID-19 infection</p>	<p>Vaccination of individuals who may be infected or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should be deferred in those with confirmed infection to avoid confusing the differential diagnosis. Ideally vaccination should be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen in those who are asymptomatic.¹</p> <p>There is no evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody.¹</p>

3.7 Experiencing 'long COVID'	Having prolonged COVID-19 symptoms [long COVID] is not a contraindication to receiving COVID-19 vaccine but if the patient is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine. ¹
3.8 Recent treatments for COVID-19	Refer to ' Interactions: Timing with COVID-19 treatments '
3.9 Recent influenza vaccine	Refer to ' Interactions: Timing with other vaccines '
3.10 Recent or imminent elective surgery	See https://www.sps.nhs.uk/articles/use-of-covid-19-vaccine-in-people-with-recent-or-imminent-elective-surgery/
3.11 Taking immunosuppressive medicines	https://www.sps.nhs.uk/articles/using-covid-19-vaccines-in-patient-taking-immunosuppressive-medicines/ See also <ul style="list-style-type: none"> • Interactions: Scheduled to begin immunosuppressive therapy • Interactions: Timing with corticosteroids • Interactions: Timing with Systemic Anti-Cancer Therapy (SACT) • Interactions: Timing with rituximab treatment • Interactions: Treated with multiple sclerosis treatments
3.12 Glucose-6-phosphate dehydrogenase (G6PD) deficiency	G6PD deficiency is not a contraindication to routine immunisation ^a <ul style="list-style-type: none"> - G6PD is not a contraindication or precaution for the AstraZeneca vaccine ³ - AstraZeneca vaccine does not contain known haemolysis triggers ^b <p>^a https://www.gov.uk/government/publications/contraindications-and-special-considerations-the-green-book-chapter-6</p> <p>^b https://bnf.nice.org.uk/treatment-summary/anaemias.html</p>

3.13 Lymphoedema	<p>The vaccine is advisable for patients with lymphoedema ^a:</p> <ul style="list-style-type: none"> • One arm affected by lymphoedema: Both doses of COVID-19 vaccine should be given in the unaffected, opposite arm. • Lymph nodes removed from the axilla (armpit) of one arm: Both doses of COVID-19 vaccine should be given in the opposite arm. • Both arms are affected by lymphoedema, but not the legs: Both doses of COVID-19 vaccine should be given into the thighs or buttocks. • Both arms and one leg is affected by lymphoedema: Both doses of COVID-19 vaccine should be given into the unaffected thigh or buttock. • Both arms and both legs are affected by lymphoedema: Both doses of COVID-19 vaccine should be given into the limb least affected by lymphoedema <p>Lymph node swelling can occur after any vaccine and is a known side effect of both Moderna and Pfizer COVID-19 vaccines. It should resolve promptly after the vaccination.</p> <p>^a https://www.lymphoedema.org/wp-content/uploads/2021/02/Consensus_Document_on_COVID_Vaccination_12feb2021.pdf (12 February 2021)</p>
3.14 Porphyria	<p>See 'Advice for patients with porphyria' https://www.sps.nhs.uk/articles/using-the-pfizer-biontech-covid-19-vaccine-in-patients-with-porphyria/</p>
3.15 Morbidly obese	<p>See 'Morbidly obese' https://www.sps.nhs.uk/articles/vaccinating-individuals-at-extremes-of-bodyweight/</p>
3.16 Low bodyweight	<p>See 'Low bodyweight' https://www.sps.nhs.uk/articles/vaccinating-individuals-at-extremes-of-bodyweight/</p>

4 Adverse effects

<p>4.1 Vaccine safety overview</p>	<p>The vast majority of suspected adverse reaction reports so far confirm the safety profile seen in clinical trials. Most reports relate to injection-site reactions (sore arm for example) and generalised symptoms such as a ‘flu-like’ illness, headache, chills, fatigue, nausea, fever, dizziness, weakness, aching muscles, and rapid heartbeat.^a Generally, these happen shortly after the vaccination and are not associated with more serious or lasting illness.^a</p> <p>See ‘Adverse effects: Risk of blood clots with lowered platelets’</p> <p>Bell’s palsy, a condition that causes temporary weakness or paralysis (lack of movement) of the muscles in one side of the face, occurs at a similar rate to the expected natural rate and does not currently suggest an increased risk.^a</p> <p>Capillary leak syndrome, a condition where blood leaks from the small blood vessels into the body, is not caused by the AstraZeneca vaccine based on current evidence.^a</p> <p>Guillain-Barre syndrome (GBS), a condition which affects the nerves, is not caused by the AstraZeneca vaccine based on current evidence. The monthly incidence of GBS in the UK is similar to that seen before the introduction of COVID-19 vaccines.^b</p> <p>^a https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting (6 May 2021)</p> <p>^b Professor Michael Lunn, National Hospital for Neurology and Neurosurgery (email; 10 May 2021)</p>
<p>4.2 Common adverse effects</p>	<p>See PHE patient information leaflet ‘What to expect after your COVID-19 vaccination’ https://www.gov.uk/government/publications/COVID-19-vaccination-what-to-expect-after-vaccination</p>
<p>4.3 Incidence and severity of adverse effects with second dose</p>	<p>When compared with the first dose, adverse reactions (both local and systemic) reported after the second dose were milder and reported less frequently. ^a</p> <p>^a Table 15 & Page 41 Error! Hyperlink reference not valid.https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/963928/UKPAR_COVID_19_Vaccine_AstraZeneca_23.02.2021.pdf</p>

<p>4.4 Risk of blood clots with lowered platelets</p>	<p>There have been reports of an extremely rare but serious condition involving blood clots and unusual bleeding after vaccination (known as vaccine induced thrombosis with thrombocytopenia; VITT):^a</p> <ul style="list-style-type: none"> • 10.5 in 1,000,000 people develop this condition after receiving a first dose of AstraZeneca vaccine^b • 2 in 1,000,000 people died from this condition after receiving a first dose of AstraZeneca vaccine^b <p>This is seen more often in younger people and tends to occur between 4 days and 4 weeks following vaccination.^a</p> <p>To understand an individual's risk/benefit of vaccination, offer PHE patient information leaflet 'COVID-19 vaccination and blood clotting' https://www.gov.uk/government/publications/covid-19-vaccination-and-blood-clotting</p> <p>Patients should seek urgent medical advice if any of the following from around 4 days to 4 weeks after vaccination:</p> <ul style="list-style-type: none"> • a new, severe headache which is not helped by usual painkillers or is getting worse • a headache which seems worse when lying down or bending over • an unusual headache that may be accompanied by: <ul style="list-style-type: none"> ○ blurred vision, nausea and vomiting ○ difficulty with your speech ○ weakness, drowsiness or seizures • new, unexplained pinprick bruising or bleeding • shortness of breath, chest pain, leg swelling or persistent abdominal pain <p>Offer PHE patient information leaflet 'What to expect after your COVID-19 vaccination' https://www.gov.uk/government/publications/COVID-19-vaccination-what-to-expect-after-vaccination</p> <p>^a https://www.gov.uk/government/publications/covid-19-vaccination-and-blood-clotting (07 May 2021) ^b https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting (6 May 2021)</p>
<p>4.5 Will the vaccine give me COVID-19?</p>	<p>No. You cannot catch COVID-19 from the vaccine but it is possible to have caught COVID-19 and not realise you have the symptoms until after your vaccination appointment.⁴</p> <p>Offer PHE patient information leaflet 'What to expect after your COVID-19 vaccination' https://www.gov.uk/government/publications/COVID-19-vaccination-what-to-expect-after-vaccination</p>

5 Excipients

5.1 List of excipients	See 'Excipients' https://www.sps.nhs.uk/articles/advising-individuals-with-allergies-on-their-suitability-for-astrazeneca-covid-19-vaccine/
5.2 Alcohol content	There is a very small amount of alcohol in the vaccine (0.002 g per dose). ³ This is not enough to cause any noticeable effects and is less than the amount of alcohol found in bread, vinegar and fruit juice. ^a The British Islamic Medical Association recommends the AstraZeneca vaccine. Refer to: ' Other questions: Islamic faith ' ^b https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5421578/
5.3 Vegan friendly or vegetarian?	The approved COVID-19 vaccines do not contain any animal, meat or egg products ⁵ VeganFriendly believe COVID-19 vaccines are vegan. PeTA recommends that vegan and animal rights campaigners take up the vaccines. Also refer to: <ul style="list-style-type: none">- 'Other questions: Catholic faith'- 'Other questions: Islamic faith'- 'Other questions: Jewish faith'

<p>5.4 Human-derived product content</p>	<p>The approved COVID-19 vaccines do not contain any animal, meat or egg products ⁵</p> <p>Non-plant based products are used in the manufacturing process however these are all filtered out and are not in the final product. The use of non-plant based products in vaccine manufacturing is common. Viruses need to grow in cells and therefore vaccine viruses are often grown in eggs (e.g. influenza vaccine) or in ‘cell-lines’ derived from mammals, including humans. Different ‘cell lines’ are effectively factories which came from an animal many years ago and have been grown in laboratories ever since. Examples vaccines using ‘cell lines’ are:</p> <ul style="list-style-type: none"> • Polio vaccine is made in ‘Vero cells’^a which originally came from the kidney of a monkey^b • Measles vaccine is made in chick embryo cells^c • Rubella vaccine is made in ‘MRC-5 cells’^c which originally came from the lung of an aborted male foetus^b • AstraZeneca COVID-19 vaccine is made in ‘HEK 293 cells’^d which originally came from the kidney of an aborted male foetus^b <p>Where ‘cell lines’ are used, these cells are lysed (disintegrated) to release the vaccine and the cell debris is filtered during vaccine production. The final vaccine product does not contain human-derived cells.^e</p> <p>Also refer to:</p> <ul style="list-style-type: none"> - ‘Other questions: Catholic faith’ - ‘Other questions: Islamic faith’ - ‘Other questions: Jewish faith’ <p>^a https://www.medicines.org.uk/emc/product/5581/smpc</p> <p>^b https://www.phe-culturecollections.org.uk/products/cellines/generalcell/search.jsp</p> <p>^c https://www.medicines.org.uk/emc/product/1159</p> <p>^d https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca</p> <p>^e https://www.sps.nhs.uk/articles/advising-individuals-with-religious-or-other-dietary-practices-and-beliefs-on-their-suitability-for-the-astrazeneca-vaccine/</p>
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6 Pregnancy and breastfeeding

6.1 Pregnancy testing prior to vaccination	See 'Pregnancy testing prior to vaccination' https://www.sps.nhs.uk/articles/using-covid-19-vaccines-in-women-of-child-bearing-potential/
6.2 Pregnancy	<p>AstraZeneca is not a preferred vaccine for pregnant women however pregnant women who commenced vaccination with AstraZeneca are advised to complete with the same vaccine¹.</p> <p>See 'Vaccination during pregnancy' https://www.sps.nhs.uk/articles/using-covid-19-vaccines-in-women-of-child-bearing-potential/</p> <p>Useful resources when consenting:</p> <ul style="list-style-type: none"> • PHE patient information leaflet: Women of childbearing age, currently pregnant or breastfeeding • RCOG Q&A: https://www.rcog.org.uk/en/guidelines-research-services/coronavirus-covid-19-pregnancy-and-womens-health/covid-19-vaccines-and-pregnancy/covid-19-vaccines-pregnancy-and-breastfeeding/ • RCOG Decision aid: https://www.rcog.org.uk/globalassets/documents/guidelines/2021-02-24-combined-info-sheet-and-decision-aid.pdf <p>Recording vaccination during pregnancy:</p> <ul style="list-style-type: none"> • <i>Where woman is known to be pregnant when vaccinated (1st or 2nd dose):</i> <ul style="list-style-type: none"> ○ Consenter should record pregnancy status on Pinnacle/NIVS, and ○ Invite woman to register with the Yellow Card Vaccine Monitor • <i>Where woman did not know she was pregnant when vaccinated, or became pregnant shortly after vaccination:</i> <ul style="list-style-type: none"> ○ HCP who the pregnant women presents to should complete Inadvertent vaccination in pregnancy notification <p>Legal mechanism for administration:</p> <ul style="list-style-type: none"> • PSD, updated PGD (AstraZeneca v2) and updated NP (AstraZeneca v2) • Older PGDs or NP do not allow for vaccination during pregnancy

6.3 Breastfeeding	<p>There is no known risk associated with giving non-live vaccines 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.¹</p> <p>Offer PHE patient information leaflet 'Women of childbearing age, currently pregnant or breastfeeding'</p>
6.4 Implications for fertility	<p>See 'Fertility and pre-conception Covid-19 vaccine advice' https://www.sps.nhs.uk/articles/using-covid-19-vaccines-in-women-of-child-bearing-potential/</p>
6.5 Implications IVF programmes	<p>See information leaflet from the British Fertility Society: https://www.britishfertilitysociety.org.uk/wp-content/uploads/2021/02/Covid19-Vaccines-FAQ-1_3.pdf</p>

7 Interactions

7.1 Timing with other vaccines	See 'Patients who received another vaccine 7 days before or after AstraZeneca COVID-19 vaccine' https://www.sps.nhs.uk/articles/interactions-information-for-astrazeneca-covid-19-vaccine/
7.2 Timing with COVID-19 treatments	See 'Time interval between treatments for COVID-19 disease (for example dexamethasone, convalescent plasma, monoclonal antibody or antiviral medicines) and vaccine administration' https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners <i>Treatments include dexamethasone, convalescent plasma, monoclonal antibody (including tocilizumab or sarilumab) or antiviral medicines (including remdesivir).²</i>
7.3 Scheduled to begin immunosuppressive therapy	See 'Patients scheduled to begin immunosuppressive therapy' https://www.sps.nhs.uk/articles/using-covid-19-vaccines-in-patient-taking-immunosuppressive-medicines/
7.4 Timing with corticosteroids	See 'Patients being treated with corticosteroids (oral, intra-articular, intra-muscular or intravenous)' https://www.sps.nhs.uk/articles/using-covid-19-vaccines-in-patient-taking-immunosuppressive-medicines/
7.5 Timing with Systemic Anti-Cancer Therapy (SACT)	See 'Patients being treated with immunosuppressive chemotherapy' https://www.sps.nhs.uk/articles/using-covid-19-vaccines-in-patient-taking-immunosuppressive-medicines/
7.6 Timing with rituximab treatment	Separate advice for rheumatology indications (see 'For rheumatology indications) and oncology indications (see 'For oncology indications') https://www.sps.nhs.uk/articles/using-covid-19-vaccines-in-patient-taking-immunosuppressive-medicines/
7.7 Treated with multiple sclerosis treatments	See 'For patient with multiple sclerosis' https://www.sps.nhs.uk/articles/using-covid-19-vaccines-in-patient-taking-immunosuppressive-medicines/

7.8 Alcohol	<p>Some news and social media have reported you should abstain from alcohol to boost your immune response to the vaccine. This is selective reporting from a statement from DrinkAware (a UK alcohol education charity).^a Their detailed recommendations:</p> <ul style="list-style-type: none">• Get vaccinated if you are offered a COVID-19 vaccine, <i>regardless of whether you ever drink any alcohol or not.</i>• Heavy drinkers have a higher risk of becoming seriously ill with COVID-19 <i>therefore please keep your appointment for vaccination if you are offered one</i>• There is no direct evidence that heavy or social drinking will affect your body's response to the COVID-19 vaccine• It is possible, but not proven, that drinking alcohol, especially regular heavy drinking, can reduce your body's response to some vaccines. Therefore it is prudent for you not to drink any alcohol for a few days before, and for at least two weeks after, you've been vaccinated. <p>Summary:</p> <ul style="list-style-type: none">• Receiving your COVID-19 vaccine without delay is important (regardless of whether you drink or not)• You may like to reduce your alcohol consumption as this is generally good for your health and there is limited evidence that it might improve your body's response to the vaccine. <p>^a https://www.drinkaware.co.uk/professionals/press/drinkaware-issues-advice-on-alcohol-and-the-covid-19-vaccine (18 January 2021)</p>
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8 Other questions

8.1 Catholic faith	https://www.cbcew.org.uk/home/our-work/health-social-care/coronavirus-guidelines/update-on-COVID-19-and-vaccination/
8.2 Islamic faith (inc. Ramadam)	See 'Muslim community' https://www.sps.nhs.uk/articles/advising-individuals-with-religious-or-other-dietary-practices-and-beliefs-on-their-suitability-for-the-astrazeneca-vaccine/
8.3 Jewish faith	See 'Jewish community' https://www.sps.nhs.uk/articles/advising-individuals-with-religious-or-other-dietary-practices-and-beliefs-on-their-suitability-for-the-astrazeneca-vaccine/
8.4 How long does the vaccine take to work?	The MHRA have said these vaccines are highly effective even with just the first dose, but to get full protection people need to come back for the second dose – this is really important. Full protection kicks in around a week or two after that second dose. ⁵
8.5 Effect of the vaccine on COVID-19 antibody tests	Vaccines teach your immune system how to create antibodies. But these are different to the ones the antibody test checks for to tell you if you've had the virus before. The COVID-19 vaccine will not affect the result of your antibody test. ^a Offer PHE patient information leaflet ' Coronavirus (COVID-19): antibody testing ' ^a https://www.gov.uk/government/publications/coronavirus-covid-19-antibody-tests/coronavirus-covid-19-antibody-tests (24 February 2021)
8.6 Implications for blood donation	Please wait 7 full days from your vaccine before donating on the 8th day. If you had side effects from the vaccine such as headache, temperature, aches and chills please wait 28 days from your recovery. ^a ^a https://www.blood.co.uk/news-and-campaigns/news-and-statements/coronavirus-covid-19-updates/
8.7 Will there be a choice of vaccines?	You will not be able to choose which vaccine you have. However, all the vaccines have been approved for use which means they are safe and effective. ⁵

8.8 South African variant	<p>There is currently no evidence that the new strains will be resistant to the vaccines we have. Viruses, such as the winter flu virus, often develop into new strains, but these new strains rarely make vaccines completely ineffective.⁵</p> <p>The South African variant is not common in the UK therefore risk of infection is low. The 'Kent' (also known as 'UK') variant however is much more common (>150 times more common^a). The AstraZeneca vaccine has been shown to be effective against the Kent variant^b therefore the vaccine will provide a high-level of protection against COVID-19 caught in the UK. The World Health Organisation recommends the AstraZeneca vaccine, even for countries who have variants present.^c</p> <p>Studies which raised concern with AstraZeneca and the South African variant were small and in a healthy young population, none of the patients in the trial developed severe COVID and so we do not know whether it is less effective at preventing severe disease.^d</p> <p>^a https://www.gov.uk/government/publications/covid-19-variants-genomically-confirmed-case-numbers/variants-distribution-of-cases-data (7 May 2021)</p> <p>^b https://www.ox.ac.uk/news/2021-02-05-oxford-vaccine-effective-against-major-b117-kent-coronavirus-strain-circulating-uk</p> <p>^c https://www.who.int/news-room/feature-stories/detail/the-oxford-astrazeneca-covid-19-vaccine-what-you-need-to-know</p> <p>^d https://www.ox.ac.uk/news/2021-02-07-chadox1-ncov-19-provides-minimal-protection-against-mild-moderate-covid-19-infection & https://www.nejm.org/doi/10.1056/NEJMoa2102214</p>
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9 Management of patients recruited into trials

9.1 COV002 (Oxford) trial

Participant need to unblind to understand their options⁶:

- <https://apps.ovg.ox.ac.uk/login/>
- Login is their participant number. Password is their DOB as an 8 digit number (DDMMYYYY)

Control arm (MenACWY vaccine)	<ul style="list-style-type: none">• Receive national rollout vaccine as normal (2 doses of vaccine)• A 2 week gap is recommended between the last dose of control vaccine and the national rollout vaccine
One dose of ChAdOx1 vaccine (either low or standard dose)	<ul style="list-style-type: none">• Receive one dose of national rollout vaccine• A 3 week gap is recommended between the last dose of ChAdOx1 vaccine and the national rollout vaccine
Two doses of ChAdOx1 vaccine (either low:low or low:standard)	<ul style="list-style-type: none">• No need to have the national rollout vaccine

Participants who were advised to not receive a booster dose of the trial vaccine should contact the site to discuss options before having a COVID-19 vaccine as part of the national rollout.

9.2 COVAC (Imperial) trial

All participants should receive national rollout vaccine as normal (2 doses of vaccine). A 4 week gap is recommended between the last dose of COVAC vaccine and the national rollout vaccine.

9.3 NOVOVAX trial

Participants are asked to contact the trials team to be unblinded before they make an appointment for a vaccine.

9.4 ENSEMBLE2 trial (Janssen; Johnson & Johnson; Ad26.COV2.S)

Participants need to unblind to understand their options therefore are asked to contact their trials team. Evidence of unbinding is needed before national rollout vaccine should be given.

Control arm (placebo)	Either: <ul style="list-style-type: none">i. Enrol onto the ENSEMBLE2 open label crossover study (subject to trial protocol amendment), orii. Receive national rollout vaccine as normal (2 doses of AZ/Pfizer/Moderna vaccine)
Ad26.COV2.S vaccine arm (1 or 2 doses)	Either: <ul style="list-style-type: none">i. No national rollout vaccine (EMA has licensed the vaccine based on a single-dose regimen), orii. Receive one dose of national rollout vaccine (anyone receiving a trial vaccine, is eligible for a single dose of national rollout vaccine, but the safety/efficacy of combining different regimens is not known). An 4 week gap is recommended between the last dose of Ad26.COV2.S vaccine and the national rollout vaccine.

10 Document management

This document is subject to constant review. If you identify any information that needs to be updated please contact admin.ncl-mon@nhs.uk.

11 Version history

Date	Version	Amendments
21 Jan 2021	1.0	New document
26 Jan 2021	1.1	Updated reference format. Removed 'administration site' query (is extensively covered in vaccinator training). [7.3 new] Specific advice for those commencing immunosuppressive therapy. [7.4 new] Specific advice for those treated with corticosteroids. [3.14 new] Specific advice for people with porphyria.
01 Feb 2021	1.2	[3.4 update] Incorporating advice from London Region (NHS E & I) Position Statement, specifically that you can vaccinate if INR <4. [6.1 new] New section offering advice in pre-conception period. [6.2 update] Removed quotes from Green Book and replaced with link to SPS website.
10 Feb 2021	1.3	[3.15 new] Added section on morbidly obese (removed section on needle size which was a duplication). [3.16 new] Added section on low body weight. [## new] Added new section on Polysorbate 80. [2.3 update] New reference. [2.4 update] New reference. [new] New information on adverse effects after second dose. [7.7 new] New section for patients treated with MS drugs. [5.4 update] Clarified that 'cell lines' are lysed before administration. [6.4 update] Removed own content and instead refer to SPS website with same message. [6.5 new] Extracted implications for IVF information from 6.4 and created a new section.
23 Feb 2021	1.4	[1.6 new] Added recommendations for children and young people. [0 updated] Added algorithms provided for allergies. [3.13 update] Updated reference and clearer advice given for lymphodema. [4.3 update] Clarified that advice appears to both systemic and local reactions. [4.1 update] Updated Yellow Card reporting. [6.5 update] New information leaflet available. [8.2 update] New information relating to vaccine administration during Ramadan. [8.8 new] New information describing the effectiveness of the vaccine against variants.
08 March 2021	1.5	Updated references. Removed 'Why has the timing of the second dose changed?' as this is not a commonly asked question anymore. Removed 'Provide staff only' section as they are now moving into second-dose workload. [4.1 update] Updated Yellow Card reporting. [8.2 update] Updated SPS website meaning that no specific link needed for vaccine administration during Ramadan.
25 March 2021	1.6	[1.1 updated] Added PHE real-world data. [1.6 updated] Specified which CYP should be vaccinated. [0 update] Major update to this section; added reference to new NCL flowchart, removed figures, removed multiple questions as covered by NCL flowchart. Removed 'Media reports of anaphylaxis' as this was many months ago. [4.1 update] Updated Yellow Card reporting. [8.8 update] Amended as new studies have been reported suggesting lack of efficacy of Oxford vaccine against South African variant [9.4 new] Advice for the J&J vaccine trial

09 April 2021	1.7	[1.6 updated] Added extenuating circumstances for not offering Pfizer to CYP in line with advice from RVOC. [3.1 new] Added new caution and contraindication section relating to coagulation disorders. [4.2 update] Updated working for very common side effects in line with PHE leaflet, now includes timelines for these common adverse effects. [4.4 new] New section for blood clots with lowered platelets. [4.1 update] Updated Yellow Card reporting. [###] Removed the specific link to Bell's Palsy and merged into the long-term adverse effects section. [6.2 update] Added the resources to support patients when consenting, added information on where to report pregnancy during vaccination, clarified legal mechanisms for supply. [8.8 update] Prevalence figures updated.
20 April 2021	1.8	[1.1 update] Change to wording not content. [1.6 update] Updated in line with revised Green Book recommendations; removed advice from RVOC '1st April 2021 - Clinical Workstream updates' as Green Book no longer recommends AZ in paediatrics. Removed advice that Pfizer is only available in PCN Hubs as work is ongoing to make available in large-scale vaccination sites. [2.1 update] Added new NCL guidance. [2.2 update] Added new NCL guidance. [3.1 new] Added new contraindication and precaution for use; added advice from Green Book which supports the contraindication but not the precaution. [4.1 update] Updated Yellow Card reporting. [6.2 update] Added new NP for AZ vaccine. [6.2 update] Added new Green Book recommendation that AZ is not recommended for pregnancy. Added new national NP. [6.3 update] Copying text from revised Green Book; no meaningful change.
23 April 2021	1.9	[3.1 update] Added advice from NHSE/I CARS that we should follow Green Book advice.
26 April 2021	1.10	[1.1 update] Minor alignment to local SOPs. [1.6 update] Formatting change only. [3.1 update] Formatting change only. [3.6 update] Formatting change only. [3.1 update] Clarified that thrombophilia is no longer a precaution for AstraZeneca vaccine. [3.12 new] New section. [4.2 update] Minor alignment to consent SOPs. [4.1 update] Major update to reflect that advice from NHSE/I is that "no long-term adverse effects" have been reported. [5.3 update] Alignment to new NHSE/I Comms FAQ and added information from PeTA and VeganFriendly. [5.4 update] Alignment to new NHSE/I Comms FAQ. [8.4 update] Alignment to new NHSE/I Comms FAQ. [###] Removed specific section on "If I have had COVID-19 should I still have the vaccine" As this is unlikely to be asked in a consent booth. [###] Removed specific question on "If I wait, will another brand of vaccine be available" as effectively covered by 8.7.
04 May 2021	1.11	[1.1 update] Added clarification that second dose is needed for long-term protection and also added the "eight week minimal interval" between doses. [1.5 new] Added section on overseas vaccinations. [1.7 new] Added section on vaccination administration error. [3.8 new] Added section on COVID-19 treatment interactions. [4.1 update] Changed the example to describe '1 in 1 million chance' to stuck by lightning in UK example. [6.2 updated] Clarifying that women who have already received 1 st dose AstraZeneca should complete the course with AstraZeneca. [7.2 new] Added section on COVID-19 treatment interactions. [8.8 update] Prevalence figures updated.

10 May 2021	1.12	[4.1 update] Changed the scope of question from 'long term' to 'overview' so reasonable to include advice about a range of conditions, including clotting, Bell's palsy and GBS. [4.2 update] Shortened advice. [4.4 update] Update with latest prevalence figures. [##] Removed question "I have been told to not get pregnant for 2 months" as latest advice is clear in section 6.2. [8.6 update] Updated advice for blood donation if you experienced adverse effects with the vaccine. [8.8 update] Prevalence figures updated.
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