

Clinical information for vaccine consenters: Moderna 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_Moderna_Information_for_vaccinators.pdf



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Key references

- [Moderna vaccine: Summary of Product Characteristics](#)
- [Specialist Pharmacy Service: Answers to Questions specific to Moderna 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 for other COVID vaccines and maximises the rate at which people can be protected:</p> <ul style="list-style-type: none"> • Trial data showed substantial protection (80%) is achieved 2 or more weeks after one dose of the Moderna vaccine^b • Real-world data with mainly Pfizer vaccine, 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>For further information, see 'Dosing schedule' https://www.sps.nhs.uk/articles/dosing-information-for-moderna-covid-19-vaccine/</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) ^b https://www.cdc.gov/media/releases/2021/p0329-COVID-19-Vaccines.html (29 March 2021) ^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 is too long</p>	<p>See 'Interval between doses is longer than recommended' https://www.sps.nhs.uk/articles/dosing-information-for-moderna-covid-19-vaccine/</p>
<p>1.3 Gap between doses was too short</p>	<p>If second dose was given:²</p> <ul style="list-style-type: none"> • 21 to 28 days after first dose: no need to repeat dose • <21 days after first dose: second dose should be discounted and another dose (a third dose) should be given at least 28 days after the dose given too early
<p>1.4 Different brand for second dose</p>	<p>See 'The same brand of vaccine is unavailable for the second dose' https://www.sps.nhs.uk/articles/dosing-information-for-moderna-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-practitioners</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 young people age 16-18 year old</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: Pfizer ¹. • Legal administration mechanism: PSD, PGD or National Protocol^a • Alternative vaccine: Moderna (off-label) ¹ can be offered 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.¹ 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) ¹ can be offered 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 chlorobutyl rubber stopper ^a ^a https://www.sps.nhs.uk/articles/advising-individuals-with-allergies-on-their-suitability-for-moderna-covid-19-vaccine/ (25 March 2021)
2.4	Allergy – thiomersal or mercury	This vaccine does not contain thiomersal (a mercury based compound) ^a ^a https://www.sps.nhs.uk/articles/advising-individuals-with-allergies-on-their-suitability-for-moderna-covid-19-vaccine/ (25 March 2021)
2.5	Allergy – food	See 'Food' (covers egg, gluten, nut & soy) https://www.sps.nhs.uk/articles/advising-individuals-with-allergies-on-their-suitability-for-moderna-covid-19-vaccine/

3 Cautions and contraindications

<p>3.1 Thrombotic disorders (inc. thrombophilia)</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><i>Note: thrombophilia includes factor V Leiden, protein C deficiency, protein S deficiency, antithrombin deficiency, antiphospholipid syndrome</i></p>
<p>3.2 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>3.3 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) ^b London Region (NHS E & I) Position Statement: Covid 19 vaccine and patients prescribed anticoagulants (8th December 2020)</p>

3.4 Acute illness (other than COVID-19 infection)	<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>
3.5 Current or previous COVID-19 infection	<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>
3.6 Experiencing 'long COVID'	<p>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</p>
3.7 Recent treatments for COVID-19	<p>Refer to 'Interactions: Timing with COVID-19 treatments'</p>
3.8 Recent influenza vaccine	<p>Refer to 'Interactions: Timing with other vaccines'</p>
3.9 Recent or imminent elective surgery	<p>https://www.sps.nhs.uk/articles/use-of-covid-19-vaccine-in-people-with-recent-or-imminent-elective-surgery/</p>

<p>3.10 Taking immunosuppressive medicines</p>	<p>https://www.sps.nhs.uk/articles/using-covid-19-vaccines-in-patient-taking-immunosuppressive-medicines/</p> <p>See also</p> <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
<p>3.11 Glucose-6-phosphate dehydrogenase (G6PD) deficiency</p>	<p>G6PD deficiency is not a contraindication to routine immunisation ^a</p> <ul style="list-style-type: none"> - G6PD is not a contraindication or precaution for the Moderna vaccine ³ - Moderna 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>
<p>3.12 Lymphoedema</p>	<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>

3.13 Porphyria	See 'Advice for patients with porphyria' https://www.sps.nhs.uk/articles/using-the-pfizer-biontech-covid-19-vaccine-in-patients-with-porphyria/
3.14 Morbidly obese	See 'Morbidly obese' https://www.sps.nhs.uk/articles/vaccinating-individuals-at-extremes-of-bodyweight/
3.15 Low bodyweight	See 'Low bodyweight' https://www.sps.nhs.uk/articles/vaccinating-individuals-at-extremes-of-bodyweight/

4 Adverse effects

4.1 Vaccine safety overview	<p>Data from the USA is reassuring ^b. Some people have no side effects whilst others have reported common side effects after COVID-19 vaccination like injection-site reactions (sore arm for example) and generalised symptoms such as fever, headache, tiredness, muscle pain, chills, and nausea ^b. Generally, these reactions are not associated with more serious illness and likely reflect an expected, normal immune response to the vaccines ^c.</p> <p>Following widespread use of Moderna vaccines across the USA ^a, no long-term complications have been reported ^{b,5}.</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.^d</p> <p>^a https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/ (03 May 2021) ^b https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html (30 April 2021) ^c https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting (29 April 2021) ^d https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html (27 April 2021)</p>
4.2 Common adverse effects	<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>
4.3 Incidence and severity of adverse effects with second dose	<p>Local and systemic adverse reactions were more frequently reported after Dose 2 than after Dose 1³</p>

<p>4.4 Risk of blood clots with lowered platelets</p>	<p>There has been no signal of ‘rare blood clots and lower platelets’ following receipt of the Moderna vaccine in the UK^a</p> <p>Whilst few patients in the UK have received in the Moderna vaccine, it accounts for a large proportion of the 229 million doses administered in the USA^b. Post-marketing experience with the Moderna vaccine in the USA has not detected this adverse effect^c.</p> <p>^a 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 (7 April 2021)</p> <p>^b https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/ (09 May 2021)</p> <p>^c https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html (30 April 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 present' https://www.sps.nhs.uk/articles/advising-individuals-with-religious-or-other-dietary-practices-and-beliefs-on-their-suitability-for-the-moderna-covid-19-vaccine/
5.2 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'
5.3 Animal- or human-derived product content	The approved COVID-19 vaccines do not contain any animal, meat or egg products ⁵ Also refer to: <ul style="list-style-type: none">- 'Other questions: Catholic faith'- 'Other questions: Islamic faith'- 'Other questions: Jewish faith'

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	See 'Vaccination during pregnancy' https://www.sps.nhs.uk/articles/using-covid-19-vaccines-in-women-of-child-bearing-potential/ Useful resources when consenting: <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 Recording vaccination during pregnancy: <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 Legal mechanism for administration: <ul style="list-style-type: none">• NP (and local PSD if/when available for use)

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 'Advice where patients receive another vaccine 7 days before or after Moderna COVID-19 vaccine' https://www.sps.nhs.uk/articles/interactions-information-for-moderna-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 considerations)	See 'Muslim community' https://www.sps.nhs.uk/articles/advising-individuals-with-religious-or-other-dietary-practices-and-beliefs-on-their-suitability-for-the-moderna-covid-19-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-moderna-covid-19-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?	No. Any vaccines that the NHS will provide will have been approved because they pass the MHRA's tests on safety and efficacy, so people should be assured that whatever vaccine they get, it is worth their while. ⁵

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 roll out.

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.COVS)

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.COVS 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.COVS 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
12 April 2021	1.0	New document
20 April 2021	1.1	[1.1 update] Change to wording not content. [1.3] Correction as previously linked to SPS website which did not provide advice for this question. [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. [4.1 update] Updated CDC references. [6.3 update] Copying text from revised Green Book; no meaningful change.
26 April 2021	1.2	[1.1 update] Minor alignment to local SOPs. [1.6 update] Formatting change only. [3.5 update] Formatting change only. [3.11 new] New section. [4.2 update] Minor alignment to consent SOPs. [4.4 update] Dropped advice to monitor for signs of VITT as it is not associated with this vaccine. [4.1 update] Major update to reflect that advice from NHSE/I is that "no long-term adverse effects" have been reported. [5.2 new] Added new section to align with AZ FAQ and added information from PeTA and VeganFriendly. [5.3 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	1.3	[1.1 update] Added clarification that second dose is needed for long-term protection. [1.5 new] Added section on overseas vaccinations. [1.7 new] Added section on vaccination administration error. [3.1 updated] Broadened from 'thrombophilia' to 'thrombotic disorders' to mirror AstraZeneca FAQ. [3.7 new] Added section on COVID-19 treatment interactions. [4.4 updated] Updated references. [4.4 updated] Updated references. [## update] Correction made. [7.2 new] Added section on COVID-19 treatment interactions.
10 May 2021	1.4	[1.1 update] Specific efficacy value added after 1 dose. [4.1 update] Changed the scope of question from 'long term' to 'overview' so reasonable to include advice about a range of conditions, including Bell's palsy. [4.2 update] Shortened advice. [4.4 update] Updated references. [##] 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.

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5. NHS England & NHS Improvement. Covid-19 frequently asked questions (v4). Published online April 2021. <https://www.england.nhs.uk/london/our-work/covid-19-vaccine-communication-materials/>
6. COV002 (Oxford) trial. IRAS Project ID: 281904 REC Ref: 20/SC/0179 COV002 Participant Email and Online Unblinding Form version 1.0. Published online December 8, 2020.