COVID-19 Vaccine – Information for Clinicians

(Supporting Patient Assessment and Frequently Asked Questions)

Based on information for currently available COVID-19 vaccines Vaxzevria® (AstraZeneca), Spikevax® (Moderna) and Comirnaty® vaccines (Pfizer-BioNTech) from various national sources available through the NHSE&I website, including guidance links to other organisations and responses from the regional Clinical Advice and Response Service (CARS).
(Excludes COVID-19 Vaccine Janssen and Nuvaxovid® as not currently supplied routinely in the UK).
Correct as of 12th July 2022

CONTENTS

1. COVID-19 Vaccine: Dose Schedule Summary

The following table provides a quick reference guide to dosing schedules for eligible cohorts. Further detail is available within this document.

Age Cohorts (no risk factors)		**Evergreen Offer**				**Notes and Vaccine Choice**
		Primary Course			**Initial Booster#**	
		1st Dose#	**2nd Dose#**	**3rd Dose#**		
5 to 15 years inclusive		✓ 12w+ from COVID-19 +ve	✓ 12w+ from 1st or COVID-19 +ve	✗	✗	# Unless otherwise specified, the interval between COVID-19 infection and COVID-19 vaccination should be 4 weeks (see section Recent COVID-19 Symptoms….).
16 to 17 years inclusive					✓ 3m+ from 2nd	
18+ years		✓	✓ 8w+ from 1st			
Risk Cohorts 1, 2, 4 & 6 (these take priority over age)		**1st Dose#**	**2nd Dose#**	**3rd Dose#**	**Initial Booster#**	**Vaccine Choice/Dose:**
5-11 years	High Risk – includes those about to commence immunosuppression	✓	✓ 8w+ from 1st	✗	✗	**5 to 11 yrs**: Comirnaty® (10 micrograms/dose) for Children 5 to 11 years
	Household contact of immunosuppressed					**12 to 17 yrs**: Comirnaty® (30 micrograms/dose) for Adults and Adolescents (further operational guidance is awaited regarding 12 year olds in school year 7)
	Severe immunosuppression in proximity to 1st or 2nd dose *(see Third Primary Dose section)*			✓ 8w+ from 2nd		**18 to 39 yrs**: mRNA
12-15 years	High Risk– includes those about to commence immunosuppression	✓	✓ 8w+ from 1st	✗	✓ 3m+ from 2nd	**40 yrs and above**: no preference for 1st or 2nd dose; mRNA for 3rd primary and booster dose
	Household contact of immunosuppressed					
	Severe immunosuppression in proximity to 1st or 2nd dose *(see Third Primary Dose section)*			✓ 8w+ from 2nd	✓ 3m+ from 3rd primary	For booster doses: see Consent and Marketing Authorisation section below for 'off label' use.
16+ years	Health and social care frontline	✓	✓ 8w+ from 1st	✗	✓ 3m+ from 2nd	Further information regarding local walk-in sites is available at NHS: Find a walk-in coronavirus (COVID-19) vaccination site.
	High Risk					
	Household contact of immunosuppressed					
	Main carer of high risk individual					Book or manage a coronavirus (COVID-19) vaccination provides up to date information regarding booking processes.
	Severe immunosuppression in proximity to 1st or 2nd dose *(see Third Primary Dose section)*			✓ 8w+ from 2nd	✓ 3m+ from 3rd primary	

Spring Booster Campaign 2022 – from 21st March 2022	
Eligible Cohort	**Spring Booster**
Adults aged 75 years and over	✓ Approximately 6 months after previous dose. Interval may be reduced to minimum of 3 months to ensure booster received during the spring campaign.
Residents in a care home for older adults	
Individuals 12 years and over who are immunosuppressed (defined in Green Book tables 3 or 4)	

2. COVID-19 VACCINATION PROGRAMME - Individual Patient Assessment Supporting Information for Responsible Clinicians

Before COVID-19 vaccination an individual patient assessment should be carried out using either:

- **Herefordshire and Worcestershire Integrated Care System: Individual Patient Assessment for the Administration of COVID-19 Vaccine or**
- **Herefordshire and Worcestershire Integrated Care System: Prompt to Support Clinical Screening on Pinnacle for the Administration of COVID-19 Vaccine in the Community**

This section is intended to support healthcare professionals, involved in the delivery of vaccination services, who are directly responsible for assessing the clinical suitability of individual patients immediately prior to vaccination.

Question	Supporting information if Red Flag answer given
Please confirm your age?	**Section 1: COVID-19 Vaccine: Dose Schedule Summary** provides a quick reference guide to dosing schedules for all eligible age cohorts. **Children and Young People (CYP):** • **Children aged 5-11 years** ○ Comirnaty® (10 micrograms/dose) for Children 5 to 11 years should be used and is supplied in a multidose vial, with each vial containing 10 doses of 10micrograms/0.2 mL (after dilution with 1.3ml of saline). ○ Fractional dosing of Comirnaty® (30 micrograms/dose) for Adults and Adolescents is no longer supported. ○ **Children aged 5 to 11 years, not in a risk group** – this is a one-off, non-urgent vaccination offer for delivery from 4th April 2022. Children will continue to become eligible as they turn five years of age until the end of August 2022. National operational guidance (*FutureNHS registration required*) provides further details. • **CYP aged 12 years and above -** Comirnaty® (30 micrograms/dose) for Adults and Adolescents should be used (30 micrograms/0.3ml of the diluted vaccine). **Note: Children aged 12 years in school year 7** ○ Further national operational guidance will be provided to support vaccination of 12 year olds in school year 7 with Comirnaty® (10 micrograms/dose) for Children 5 to 11 years. This change is not expected to be implemented until late April 2022. **Notes:** • The NP and PGD for Comirnaty® 10micrograms/dose for Children 5 to 11 years may be used for individuals aged: ○ 5 to 11 years, not in a risk group (one-off programme) ○ 5-11 years in a risk group ○ 12 years and under, and in school year 7 ○ 12 years who commenced, but did not complete a primary course, with Comirnaty® (10 micrograms/dose) for children 5 to 11 years ○ 12 years who commenced, but did not complete a primary course, with a fractional 10 microgram dose of Comirnaty® (30 micrograms/dose) for adults and adolescents • The NP and PGD for Comirnaty® (30 micrograms/dose) for Adults and Adolescents may be used for individuals: ○ Aged 12 years and older • **Vaccinators need to be clear which PGD or Protocol they are working to, depending on the available stock and age of patient, and ensure they give the patient the correct patient information leaflet.** • Please refer to separate Second Dose Scheduling, Third Primary Dose and Booster Vaccine Programme for further details including PGD/NP inclusion criteria. • For information on management of individuals with history of recent COVID-19 infection see section below Recent COVID symptoms, asymptomatic with COVID positive PCR test result or currently required to self-isolate? • Comirnaty® vaccines are the preferred choice for children and young people under 18 years, as they have the most extensive safety data and lower reported rates of myocarditis.

Question	Supporting information if Red Flag answer given
	○ Comirnaty® (30 micrograms/dose) for Adults and Adolescents has been authorised for use from 12 years old. ○ Comirnaty® (10 micrograms/dose) for Children 5 to 11 years has been authorised for children aged 5 to 11 years. • Vaxzevria® (AstraZeneca) vaccine – is not authorised for use in patients less than 18 years old, and these patients are not covered by the PGD or NP. • Spikevax® (Moderna) vaccine – is authorised for use in individuals 6 years and older; however, patients aged under 18 years are not covered by the PGD or NP. Green Book advice remains that Comirnaty® vaccines should be offered to children and young people. • Clinical detail regarding CYP risk groups is available in the Green Book. • Resources for children and young people have been updated including a consent form. • **Operational Readiness Checklists A, B and C** *(FutureNHS registration required)***-** The following checklists should be used by sites to identify any potential gaps in service provision for vaccinating eligible under 18 year olds: ○ **Checklist A Children 16 and 17 years of age** - MVC (including Community Pharmacy sites) require completion of self-assessment and declaration on Qflow. Note: PCN sites are strongly encouraged to review and ensure they are compliant. ○ **Checklist B Children 12 to 15 years of age -** All sites vaccinating this age group CYP must meet the requirements of Checklist B. ○ **Checklist C Children 5 to 11 years** – All sites vaccinating this age group must meet the requirements of readiness checklist C. **Adults younger than 40 years of age without underlying health conditions (that increase the risk of COVID-19) – updated JCVI guidance (when eligible for vaccination) states:** • Unvaccinated adults should be preferentially offered an alternative to Vaxzevria® (AstraZeneca) COVID-19 vaccine, where possible and only where no substantial delay or barrier in access to vaccination would arise. • For those under 40 years who are of older age (over 30 years), male, obese (BMI above 30), from certain ethnic minority backgrounds or experiencing socio-economic deprivation, the risks of acquiring and/or suffering complications of COVID-19 are higher. Every effort should be made to remove barriers to accessing vaccination in those individuals. • For those aged 18 to 29 years the precautionary advice for a vaccine preference is stronger, reflecting a gradient in the benefit-risk balance with age. • For further information regarding the Vaxzevria® (AstraZeneca) COVID-19 vaccine and clotting risk see 'Bleeding or Clotting Disorder' section below. **Please refer to separate Second Dose Scheduling, Third Primary Dose and Booster Vaccine Programme for further details.**
Thrombosis and thrombocytopenia syndrome (TTS) – Major venous and/or arterial thrombosis with thrombo-cytopenia including Heparin Induced Thrombo-cytopenia (HITT or HIT type 2) Note: National advice is emerging,	**For further information see:** • **UKHSA Information for healthcare professionals on blood clotting following COVID-19 vaccination** • **HWICS Clinical Guidance Notice: Blood Clotting, Headache and COVID-19 Vaccination** **Vaxzevria® (AstraZeneca) COVID-19 vaccine and risk of clotting** MHRA and JCVI state that the balance of risk remains very much in favour of vaccination. **First doses** **Individuals 40 years of age and over and those of any age who have underlying health conditions which put them at higher risk of severe COVID-19 disease:** • The benefits of prompt vaccination with the Vaxzevria® (AstraZeneca) COVID-19 vaccine far outweigh the risk of adverse events for individuals 40 years of age and over and those who have underlying health conditions which put them at higher risk of severe COVID-19 disease. • Therefore, eligible recipients who are scheduled to receive a first dose of Vaxzevria® (AstraZeneca) vaccine should continue with consent obtained in line with the recommendations set out in the Green Book.

Question	Supporting information if Red Flag answer given
and this guidance may change	**Adults under 40 without underlying health conditions:** • Unvaccinated adults <40 years, should be preferentially offered an alternative to the Vaxzevria® (AstraZeneca) COVID-19 vaccine. • Those individuals under 40 years, who are of older age (over 30 years), male, obese (BMI above 30), from certain ethnic minority backgrounds, or in certain occupations at high risk of exposure, remain at high risk of COVID-19. In the **absence of a suitable alternative*** these individuals should still be offered the AstraZeneca vaccine, and may choose to receive the vaccine, provided they have been informed and understand the relative risks and benefits. They should be given the latest version of the COVID-19 vaccination and blood clotting leaflet. *This is defined as availability across the counties of Herefordshire and Worcestershire and does not apply to individual sites. For those aged 18 to 29 years the precautionary advice for a vaccine preference is stronger, reflecting a gradient in the benefit-risk balance with age. **Second doses and boosters** • The Green Book, chapter 14a states that current evidence supports the decision to complete the primary course or boost patients with a history of TTS with an mRNA vaccine, provided at least 12 weeks has elapsed from the implicated dose. • If there are concerns regarding further vaccination, then discussion with a haematology consultant via the Advice and Guidance service is advised. **Individuals with contraindications or conditions that require special precautions:** Full details listed in Regulatory Approval for Vaxzevria® (AstraZeneca) vaccine: • **Contraindications** (CI) – Regulatory Approval for Vaxzevria® (AstraZeneca) vaccine lists a history of major venous and/or arterial thrombosis occurring with thrombocytopenia following vaccination. UKHSA Blood Clotting Information for Healthcare Professionals states that CI "include individuals who have a history of heparin-induced thrombocytopaenia and thrombosis (HITT or HIT type 2)". • **Cautions** – Regulatory Approval for Vaxzevria® (AstraZeneca) vaccine states that vaccination in patients with a history of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2), or cerebral venous sinus thrombosis should only be considered when the potential benefit outweighs any potential risks. **Notes:** **1. A history of thrombosis or thrombocytopenia on its own is not a contraindication to the vaccine.** In the absence of low platelets with a blood clot event being recorded in the patient's medical records, such individuals can be offered the Vaxzevria® (AstraZeneca) vaccine. **2. History of immune thrombocytopenia (ITP) is not a contraindication for COVID-19 vaccination, but platelet monitoring is advised.** UK ITP Forum Working Party guidance advises that all patients who have a history of ITP or ITP relapse post COVID-19 vaccination may receive COVID-19 vaccination with any appropriate COVID-19 vaccine, ensuring the following actions: a. Individual risk assessment (MVC to consider need for GP/PCN referral) b. Patient discussion regarding the potential for a fall in platelet count/relapse. The UK ITP Forum patient advice leaflet can support these discussions. c. A platelet count check 2-5 days after vaccination (MVC to ensure patient contacts GP) Notes: • The above recommendations are also included in the regulatory approval for Vaxzevria® (AstraZeneca). • For individuals who experience ITP post COVID-19 vaccination: a. Patients should be managed in line with usual practice b. Guidance should be sought from a haematologist regarding risk benefit of further vaccinations. • This applies only to patients with a confirmed diagnosis of ITP or thrombocytopenia in association with another auto-immune condition. Individuals with mild thrombocytopenia which has not been investigated can be vaccinated as normal. **3. Individuals diagnosed with thrombocytopenia within 3 weeks after vaccination with Vaxzevria® (AstraZeneca) COVID-19 vaccine should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis**

Question	Supporting information if Red Flag answer given
	within 3 weeks after vaccination should be evaluated for thrombocytopenia. The HWICS Clinical Guidance Notice: Management of Blood Clotting, Headache and COVID-19 Vaccination provides specific guidance on investigation and management of these patients. 4. **Aspirin should NOT be taken before vaccination with AstraZeneca vaccine, unless this is already part of a patient's regular medications.** Aspirin is not currently thought to have the same reduction in clotting risk in this condition and may in fact worsen the outcome by increasing the risk of bleeding. **Healthcare professionals should ensure the following:** • Everyone who presents for vaccination is asked about additional risk factors, using the materials provided by UK Health Security Agency (UKHSA, previously Public Health England) • If they are greater than 40 years and at increased risk of clotting: o They should have a discussion about the benefit and risks to them of receiving Vaxzevria® (AstraZeneca) or other vaccine with a clinician. o If, following a conversation with a clinician, an individual chooses to go ahead with Vaxzevria® (AstraZeneca) vaccination, vaccination sites should make this option available. However, it is essential that informed consent is given and carefully documented o If an individual chooses to have another vaccine, then they should be rebooked in a clinic offering an alternative vaccine. • If they are less than 40 years: o Wherever possible individuals <40 years should be rebooked into a clinic offering an alternative vaccine. o Alternative vaccines are locally available. o If, in the **absence of a suitable alternative*,** following a conversation with a clinician, the risk vs benefit of immediate vaccination with Vaxzevria® (AstraZeneca) vaccine is **clinically** favourable, vaccination can proceed. However, it is essential that informed consent is given and carefully documented *This is defined as availability across the counties of Herefordshire and Worcestershire and does not apply to individual sites. Further information for healthcare professionals and patients has been provided by UKHSA and within Frequently Asked Questions: MHRA and JCVI guidance on Vaxzevria® (AstraZeneca) COVID-19 vaccine and very rare clotting disorders. HWICS Clinical Guidance – Blood Clotting, Headache and COVID-19 Vaccination provides local guidance. The Faculty of Sexual and Reproductive Healthcare has issued guidance on AstraZeneca COVID-19 vaccine, combined hormonal contraception and blood clots. This recommends that "**people, including combined hormonal contraceptive users, attend for their COVID-19 vaccination when it is offered, and do not delay it to wait for a specific type of vaccine**". The press release discusses the risks and benefits of hormonal contraception, COVID-19 infection and COVID-19 vaccine. It also advises that combined hormonal contraception users **do not stop using their contraceptive pill, patch or vaginal ring** when they are called for vaccination as it will not help and will put them at risk of pregnancy.
Vaccines or injection within the last 7 days?	**Administration of other vaccines should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events.** • There is no data on the co-administration with COVID-19 vaccines. • In the absence of such data first principles suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. • Similar considerations apply to co-administration of inactivated COVID-19 vaccines with live vaccines such as MMR. • There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. • If vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects

Question	Supporting information if Red Flag answer given

	Patients who attend having received a vaccine in the last 7 days or present requiring immunisation with two or more different vaccines:
	• Currently available COVID-19 vaccines are considered inactivated (including the non-replicating adenovirus vaccine)
	• **COVID-19 vaccination should still be given when individuals in an eligible cohort present:**
	  ○ having received one or more inactivated or another live vaccine in the last 7 days
	  ○ for another live or inactivated vaccine within 7 days of a COVID-19 vaccine
	  ○ requiring immunisation with two or more different vaccines on the same day
	Note:
	• This includes but is not limited to vaccines commonly administered around the same time or in the same settings (including influenza and pneumococcal polysaccharide vaccine in those aged over 65 years, pertussis-containing vaccines and influenza vaccines in pregnancy, and live attenuated influenza vaccine (LAIV), HPA, MenACWY and Td-IPV vaccines in the schools programmes).
	• **The only exceptions to this are the shingles vaccines** (live and non-live), where a seven-day interval should ideally be observed given the potential for an inflammatory response to COVID-19 vaccine to interfere with the response to the live virus in the older population and because of the potential difficulty of attributing the systemic side effects to the newer adjuvanted shingles vaccine.
	• **It is generally better for vaccination to proceed and may be provided under all currently available COVID-19 vaccine PGDs or NPs, to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment.** In such circumstances, patients should be informed about the likely timing of potential adverse events relating to each vaccine.

Unwell with fever?	• **Minor illness/infection without fever or systemic upset are not contraindications to immunisation and patients should be vaccinated.** • **If an individual is acutely unwell, immunisation should 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. • In case of postponement due to acute illness, advise when the individual can be vaccinated and if possible, ensure another appointment is arranged. • **Individuals with acute severe febrile illness are excluded under all currently available COVID-19 vaccine PGDs and NPs.**

Prior systemic allergic reaction to a previous dose of COVID-19 vaccine, or any component of or residues from the manufacturing process?
 	
History of immediate onset anaphylaxis to multiple classes of drugs?
 	
Unexplained anaphylaxis?
	Please refer to HWICS Clinical Guidance Notice: COVID-19 Vaccine – Managing Individuals with a History of Allergy and HWICS History of Allergy: COVID-19 Vaccine Site Referral For Review Template for local guidance.
	Please refer to the Green Book for full up to date allergy guidance and specific flow-charts to help guide:
	• Management of patients with a history of allergy (table 5)
	• Flowchart for managing patients who have allergic reactions to a previous dose of COVID-19 vaccine
	
	Suspension of 15min Wait Following Vaccination with a mRNA Vaccine
	• On the 5th May 2022 the MHRA and the Commission on Human Medicines formally removed the 15-minute observation period following vaccination with a mRNA vaccine for individuals aged 12 years and over without a history of allergy (as outlined in the Green Book.)
	• A temporary suspension of the 15-minute observation period for children aged 5-11 years remains in place (this will be reviewed on a regular basis).
	
	Following vaccination with all COVID-19 vaccines individuals should be:
	  ○ Observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre.
	  ○ Informed of signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms.
	• In some settings, for example domiciliary vaccination, it may be appropriate for a responsible adult to be present for at least 15 minutes after vaccination.
	• No specific management is required for patients with a family history of allergies.

Question	Supporting information if Red Flag answer given

	• Patients with a personal history of allergy should be managed in accordance with table 5 in the Green Book. **Individuals with the following history can proceed with vaccination in any setting, but a 15 min observation period should be considered:**
	  ○ previous allergic reaction (including anaphylaxis) to a food, insect sting and most medicines (where trigger has been identified)
	  ○ previous non-systemic reaction to a vaccine
	  ○ hypersensitivity to non-steroidal anti-inflammatory drugs e.g. aspirin, ibuprofen
	  ○ mastocytosis
	• Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting. **Observation for 15 minutes is recommended.**
	
	Contraindications to currently available vaccines (as stated in the regulatory authorisations) include:
	• Hypersensitivity to the active substance or to any of the excipients
	
	The Green Book provides further guidance regarding management of patients, stating that the following are relative contraindications to receiving a COVID-19 vaccine:
	• **a previous systemic anaphylactic reaction to a COVID-19 vaccine**
	  ○ individuals who received Vaxzevria® (AstraZeneca) vaccine may be given an alternate vaccine in any setting, with observation for 30 minutes
	  ○ many individuals with initial apparent allergic reactions to a mRNA vaccine can tolerate a second dose of the same vaccine.
	  ▪ If no objective signs of anaphylaxis and symptoms rapidly resolved (with no more than 1 dose of IM adrenaline), a further dose of the same vaccine can be given in any vaccination setting, with observation for 30 minutes.
	  ▪ If the reaction may have been anaphylaxis, obtain expert advice; if a decision is made to administer the same vaccine, then this should be done under medical supervision in the hospital setting.
	• **A prior allergic reaction to any component (excipient) of the COVID-19 vaccine e.g. polyethylene glycol (PEG) and polysorbate 80.** Refer to Summary of Product Characteristics for each product for a full list of excipients)
	  ○ A very small number of individuals have experienced anaphylaxis when receiving a COVID-19 vaccine. Anyone with a history of allergic reaction (systemic) to an excipient in the COVID-19 vaccine should not receive that vaccine (except with expert advice), but those with any other allergies (such as a food allergy) – including those with prior anaphylaxis – can have the vaccine.
	  ○ The mRNA vaccines contain polyethylene glycol (PEG). PEGs (also known as macrogols) are a group of known allergens commonly found in medicines, many household products and cosmetics. Medicines containing PEG include some tablets, laxatives, depot steroid injections, and some bowel preparations used for colonoscopy. Known allergy to PEG is rare. Evidence now shows that PEG allergy is implicated in only a minority of allergic reactions reported after COVID-19 vaccines. Advice for children with cancer who may be receiving PEG containing drugs is available Coronavirus advice (cclg.org.uk).
	  ○ Published data now show that some individuals with prior allergic reaction to PEG-containing medicines (e.g. PEG-asparaginase) can tolerate the Comirnaty® vaccines. Expert advice should be obtained and if a decision is made to administer an mRNA vaccine, then this should only be done in hospital under medical supervision.
	
	Additional exclusions under the vaccine PGDs and NPs are:
	• Previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of a COVID-19 mRNA vaccine (Spikevax® (Moderna) and Comirnaty® vaccines only)
	• Previous systemic allergic reaction to residues from the manufacturing process (all currently available COVID-19 vaccines.
	Notes:

Question	Supporting information if Red Flag answer given
	• A longer observation period of 30 minutes may be necessary for any vaccine administered in any setting if there is clinical concern; for example, people with Hereditary angioedema (HAE), an autosomal-dominant disease which causes a deficiency in C1-esterase inhibitor function. • A protocol for the management of anaphylaxis and an anaphylaxis pack must be available at all vaccination centres. Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml adrenaline), with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis. • For further local guidance refer to COVID-19 Vaccine: Anaphylaxis Medication and Equipment Requirements. • Further information on advising individuals with allergies on their suitability for vaccine is available for Vaxzevria® (AstraZeneca), Spikevax® (Moderna) and Comirnaty® vaccines. • As fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should not drive for 15 minutes after vaccination. • Please report any suspected adverse reactions via the Yellow Card scheme. To make a report or find out more about the Yellow Card COVID-19 reporting site please visit: Coronavirus Yellow Card reporting site.
Heparin Induced Thrombo-cytopenia (HITT or HIT type 2)	See Major venous and/or arterial thrombosis with thrombocytopenia section
Pregnant or could be pregnant?	**Pregnancy (all stages) is now considered a clinical risk factor for severe COVID-19 infection. All pregnant women should be offered COVID-19 vaccination, in line with other high-risk groups. They should undergo an individual risk benefit assessment with a healthcare professional to discuss the latest evidence on safety and choice of COVID-19 vaccine.** **The Green Book states that:** • **mRNA vaccines are the preferred choice for pregnant women** (for those under 18 years, Comirnaty® vaccines are preferred) **as there is now extensive post-marketing experience in the USA with no safety signals so far.** • Clinical trials on the use of COVID-19 vaccines during pregnancy are not advanced, however available data does not indicate any harm to pregnancy. • **Pregnant women should be offered primary and reinforcing (booster) vaccination in line with high-risk groups.** • Initial analysis of birth outcomes in women who had received at least one dose of COVID-19 vaccine and delivered between January and November 2021 in England showed a similar or higher rate of good birth outcomes than in unvaccinated women. • Although pregnancy increases the risk of clotting conditions, there is no evidence that pregnant women, those in the post-partum or women on the contraceptive pill are at higher risk of the specific condition of thrombosis in combination with thrombocytopaenia after the Vaxzevria® (AstraZeneca) vaccine. There have been no confirmed cases reported in pregnant women to date. **NHSE&I letters provide additional details:** **First Doses:** • All healthcare professionals have a responsibility to proactively encourage pregnant women to get vaccinated against COVID-19. • Pregnant woman who have yet to receive a COVID-19 vaccination, should be offered mRNA vaccines (for those under 18 years, Comirnaty® vaccines are preferred). • 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. • COVID-19 infection in pregnancy carries a significant risk of hospital admission and a higher risk of severe illness than for the non-pregnant population – especially so in the third trimester – and a higher risk of preterm birth. Recent data now shows that nearly 20% of all patients with COVID-19 infection who require Extra Corporeal Membrane

Question	Supporting information if Red Flag answer given
	Oxygenation (ECMO) are pregnant and unvaccinated, and that the proportion of pregnant women requiring ECMO has risen substantially. • Healthcare professionals should discuss the risks and benefits of vaccination (including the latest evidence on safety and choice of COVID-19 vaccine) with each pregnant woman presenting for vaccination, as part of the pre-vaccination clinical assessment and consent process, escalating discussions to clinical site lead where necessary. • 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. • 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. **Second doses:** • Pregnant women who have already received a dose of Vaxzevria® (AstraZeneca) vaccine can complete with the same vaccine or with an mRNA product (unless contraindicated). • Where the first dose was from the Vaxzevria® (AstraZeneca) vaccine, women should also consider the information in the COVID-19 vaccination and blood clotting leaflet. • UKHSA advice recommends that second doses should not be delayed. **The COVID-19 vaccination in pregnancy: vaccinator checklist,** (updated 19th May 2021) **provides further advice and should be used by health professionals obtaining consent at vaccination sites for all women of childbearing age:** • Ask whether the woman is or might be pregnant. Record the response in the point of care IT system. If the woman is pregnant and is aware of her estimated date of delivery, please record this. • If the woman is pregnant, or thinks she might be, and is attending for her first dose, she should be offered an mRNA vaccine. If your site doesn't offer these vaccines, advise the woman that she should rebook through the National Booking System. • If the woman received a first dose of Vaxzevria® (AstraZeneca) and is attending for her second dose, she may complete with the same vaccine or with an mRNA product (unless contraindicated). • If the woman is pregnant, or thinks she might be, give the woman the UKHSA and RCOG information leaflets. Offer pre-vaccination counselling on the potential benefits and risks of vaccination in line with the UKHSA and RCOG documents so that the woman has the opportunity to make an informed decision about her vaccination on-site. Document this in the point of care IT system. • If the woman has any further questions or concerns that she would like to resolve before consenting to vaccination, follow the local pathway to obtain immediate advice from the site clinical lead, or refer the woman to her GP, or a healthcare professional in her maternity service, for timely advice. • If the woman is unsure whether she is pregnant and has concerns about this, she may wish to consider confirming pregnancy status prior to making a decision. JCVI does not advise routine pregnancy testing before receipt of a COVID-19 vaccine. • If the offer of vaccination is accepted, record that informed consent has been obtained before administering the vaccine. Signpost women to the MHRA's Yellow Card Vaccine Monitor information. • If vaccination is to proceed, it is covered by PGDs and NPs for all COVID-19 vaccines. **Additional points:** • The Summary of Product Characteristics for Spikevax® and Comirnaty® vaccines state that they can be used during pregnancy. • The authorisations for use of Vaxzevria® (AstraZeneca) vaccine states that vaccine administration in pregnancy "should only be considered when the potential benefits outweigh any potential risks for the mother and foetus". • Routine questioning about last menstrual period and/or pregnancy testing is not required before offering the vaccine. However all women of childbearing age being invited for vaccination should be provided with the advice in the leaflet UKHSA COVID-19 vaccination: a guide on pregnancy and breastfeeding and their

Question	Supporting information if Red Flag answer given
	understanding checked as part of the consent process (UKHSA COVID-19 vaccination consent form). Additional measures may need to be considered for potential recipients who are unable to access the information in written or online form. • Pregnant women are more likely to have severe COVID-19 infection if they are overweight or obese, are of Black and Asian Minority Ethnic background, have co-morbidities such as diabetes, hypertension and asthma, or are 35 years old or older. • Those who are trying to become pregnant do not need to avoid pregnancy after vaccination. • If a woman finds out she is pregnant after she has started a course of vaccine, she should complete vaccination during pregnancy at the recommended interval. • Termination of pregnancy following inadvertent immunisation is not recommended. • The Royal College of Obstetricians and Gynaecologists (RCOG) have produced several COVID-19 vaccines and pregnancy resources including Q&As on pregnancy, fertility and breastfeeding, as well as an updated information leaflet and decision aid to support women to make a personal informed choice, in discussion with a healthcare professional. • The Lowdown on the COVID-19 Vaccine, Periods and Fertility – a patient friendly resource created in partnership with the NHS. • UKHSA Inadvertent Vaccination in Pregnancy (VIP) guidance and notification forms have now been updated to include COVID-19 vaccines. All **inadvertent** vaccination of women who are pregnant or in the weeks prior to becoming pregnant should be reported via this route for surveillance purposes. • The Green Book summarises the available evidence.
Breast feeding?	**Breastfeeding women may be vaccinated with all currently available COVID-19 vaccines under the respective PGD or NP.** • There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with any suitable COVID-19 vaccine. • The developmental and health benefits of breastfeeding are clear and should be discussed with the woman, along with the woman's clinical need for immunisation against COVID-19. • Emerging safety data is reassuring; mRNA was not detected in the breast milk of recently vaccinated women and protective antibodies have been detected in breast milk. • The Summary of Product Characteristics for Spikevax® and Comirnaty® vaccines state that they can be used during breastfeeding. • The leaflet UKHSA COVID-19 vaccination: a guide on pregnancy and breastfeeding is available to support discussions.
Previous or planned COVID-19 vaccine?	**Individuals excluded from vaccination include individuals who:** • **Have received a dose of COVID-19 vaccine in the preceding 21 days (Comirnaty® vaccines) or 28 days (Vaxzevria® (AstraZeneca) and Spikevax® (Moderna))** For **Comirnaty® vaccines**, where the second dose is administered **less than 19 days** from the first dose, the dose should be discounted, and a third dose administered at least 21 days after the second dose. If this situation arises, the 'third dose' cannot be supplied under the Comirnaty® vaccines PGD or NP. Instead, a Patient Specific Direction (PSD) would be required to enable the administration of a third dose. For **AstraZeneca vaccine**, where the second dose is administered **less than 21 days** after the first, it should be discounted, and a third dose administered at least 8-12 weeks after the second dose. If this situation arises, the third dose cannot be supplied under Vaxzevria® (AstraZeneca) PGD or NP. Instead, a PSD would be required to enable the administration of a third dose. For the **Spikevax® (Moderna) vaccine**, where the second dose is administered **less than 21 days** after the first, it should be discounted, and a third dose administered at least 28 days after the second dose. If this situation arises, the third dose cannot be supplied under the Spikevax® (Moderna) PGD or NP. Instead, a PSD would be required to enable the administration of a third dose. **Note**: • National guidance has recently been updated to include third doses for eligible individuals. For further details see sections below: Third Primary Dose and Booster Vaccine Programme for winter 2021 to 2022.

Question	Supporting information if Red Flag answer given
	Participation in a Clinical Trial of COVID-19 Vaccines: • Individuals who have participated in a clinical trial of COVID-19 vaccines should be provided with written advice on whether and when they should be safely vaccinated in the routine programme. • Advice should also be provided from the trial investigators on whether any individual should receive additional doses for the purposes of vaccine certification. • Vaccine clinical trial participants may receive additional vaccine doses to ensure they can travel abroad to countries that only accept vaccination records for COVID-19 vaccines approved for deployment. For further details see section below: FAQ 4 COVID-19 vaccine clinical trialist – requesting revaccination • Trial participants who are eligible for boosters should be offered vaccination in line with the general population, at least three months after the dose considered as the final primary dose or the final revaccination (if the latter is required for certification purposes). • If vaccination is to proceed, it is covered by PGDs and NPs for all COVID-19 vaccines. **Vaccination Course Interruption or Delay:** • Where this occurs, vaccination should be resumed using the same vaccine, but the first dose should not be repeated. Individuals who started the schedule and who attend for vaccination where the same vaccine is not available or suitable, or if the first product received is unknown, one dose of the locally available product should be given to complete the primary course. • This includes patients who contract COVID-19 or who are required to self-isolate between their first and second vaccination dose and in whom delay is necessary (see section below for further information). **Vaccination by Different Providers/Alternative COVID-19 Vaccines:** • Evidence suggests that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines make a good immune response, although rates of side effects with a heterologous second dose are higher. • Accumulating evidence now supports the use of heterologous schedules for primary immunisation, and these are now recognised by the European Medicines Agency. • For individuals who started the schedule and who attend for vaccination where the same vaccine is not available or suitable, or if the first product received is unknown, one dose of the locally available product should be given to complete the primary course. • Individuals who experienced severe expected reactions, after a first dose of Vaxzevria® (AstraZeneca) or Comirnaty® vaccines should be informed about the higher rate of such reactions when they receive a second dose of an alternate vaccine.

Anticoagulant therapy?	**The Green Book states individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR is below the upper level of the therapeutic range, can receive intramuscular vaccination.**
	Stable anticoagulation therapy includes:
	• direct oral anticoagulant (apixaban, dabigatran, edoxaban & rivaroxaban) or
	• warfarin -
	  ○ individuals should be up to date with their scheduled INR testing and
	  ○ latest INR should be below the upper level of the therapeutic range i.e. INR<4 or
	• treatment dose heparin (weight dependent) or fondaparinux injections
	Key points:
	• **The currently available COVID-19 vaccines are not contraindicated for patients on anticoagulation. The risk is due to the use of intramuscular injection.**
	• There is an increased risk of bruising at the injection site, however serious effects related to anticoagulation are not anticipated. The individual/parent/ carer should be informed about the risk of haematoma from the injection.
	• A fine needle (23 or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site without rubbing for at least 2 minutes (Green Book) – *Note the needles for administration supplied with the current COVID-19 vaccines are 23 gauge.*

Question	Supporting information if Red Flag answer given
	• If the registered professional clinically assessing the individual is not the vaccinator, they must alert the vaccinator to the increased risk of haematoma and the need to apply firm pressure to the injection site for at least 2 minutes. • Patients on warfarin with supra therapeutic INR should wait until their INR is <4.0 • If in doubt, consult the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy.
Bleeding or clotting disorder?	**Patients with inherited bleeding disorders such as Haemophilia should seek advice from their own Haemophilia Centre to ensure they receive the vaccine safely.** The Green Book states that: • Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. • If the individual receives medication/ treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/ treatment is administered. **Key points:** • Individuals with thrombocytopenia or a bleeding disorder may develop a haematoma at the injection site. The individual/parent/carer should be informed of the risk. • A fine needle (23 or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site without rubbing for at least 2 minutes (Green Book) – *Note the needles for administration supplied with the current COVID-19 vaccines are 23 gauge.* • If the registered professional clinically assessing the individual is not the vaccinator, they must alert the vaccinator to the increased risk of haematoma and the need to apply firm pressure to the injection site for at least 2 minutes.
Recent COVID symptoms, asymptomatic with COVID positive PCR or lateral flow test result	**Confirmed COVID-19 Infection:** • **Vaccination should be deferred in those with confirmed infection to avoid onward transmission and to avoid confusing the differential diagnosis.** • As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until clinical recovery, see 'Past History of COVID-19 Infection' below for further guidance. • Vaccination of individuals who may be infected, asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. **Self-isolating Individuals:** • Those currently self-isolating should not receive vaccination until the end of the self-isolation period – this includes all staff required to self-isolate as a result of a workplace outbreak of COVID-19. Staff unaffected by their workplace outbreak may be immunised. **Prolonged COVID-19 Symptoms:** • Are 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. **Past History of COVID-19 Infection:** • There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical and epidemiological features to suggest the episode was COVID-19 infection. • For individuals who have had proven COVID-19 infection any subsequent COVID-19 vaccination should ideally be deferred until: ○ twelve weeks from onset (or sample date) for those under 18 years of age who are not in a risk group (cohorts 1,2, 4 and 6) Note: When advised via national operational letter, this interval may be reduced to eight weeks in healthy under 18 year olds when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. ○ four weeks from onset (or sample date) for individuals in a risk group (cohorts 1,2, 4 and 6) and all those over 18 years of age Note: When advised via national operational letter, this interval may be reduced to ensure operational flexibility when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. For care home residents and the housebound, there may be advantage in offering

Question	Supporting information if Red Flag answer given
	vaccination to those with recent confirmed COVID-19, without a four-week deferral, where individuals are clinically stable and infection control procedures can be maintained. These populations are likely to be highly vulnerable and this will facilitate vaccination without the need for multiple visits. **All COVID-19 vaccine PGDs and NPs include administration at shorter intervals when advised nationally.** • In younger people protection from serious complications of COVID-19 infection is likely to be high for a period of months following COVID-19 infection. Limited evidence suggests countries with longer intervals between primary doses (eight to twelve weeks) have lower rates of myocarditis after the second dose. • There is no convincing evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibodies. • No specific interval is required between receipt of monoclonal antibodies used for the treatment or prophylaxis of COVID-19 infection and COVID-19 vaccination, or vice versa.
Immuno-compromised or receiving immune-suppressant therapy?	For individuals who were severely immunosuppressed when they received their first or second COVID-19 vaccination or who are currently immunosuppressed see separate sections Third Primary Dose and Booster Vaccine Programme below as appropriate. **Vaccination prior to initiation of highly immunosuppressive interventions** • Individuals who are about to receive immunosuppressive interventions or those whose level of immunosuppression is about to increase should be considered for vaccination prior to commencing therapy, if therapy can be safely delayed or there is sufficient time, when their immune system is better able to make a response. • Where possible, it is preferable for the 2-dose schedule to be completed prior to commencing immunosuppression. This would entail offering the second dose at the recommended minimum interval for that vaccine (Vaxzevria® (AstraZeneca) 8 weeks, Spikevax® (Moderna) 4 weeks, Comirnaty® vaccines 3 weeks) to provide maximum benefit that may not be received if the second dose was given during the period of immunosuppression. • The booster should be brought forward for those about to receive immunosuppressive treatment to avoid giving the booster when the immune system is less able to respond. See section below 'Booster Vaccine Programme' for further details. • Any decision to defer immunosuppressive therapy or to delay possible benefit from vaccination until after therapy should not be taken without due consideration of the risks from COVID19 and from their underlying condition. • Please refer to Action Notice: Early Access to COVID-19 Vaccination Pre-Immunosuppressive Therapy for local guidance. **Vaccination of people living with individuals who have weakened immune systems** • The JCVI has advised that children and young people aged 5 years and over, who are household contacts of persons (adults or children) who are immunosuppressed, should be offered COVID-19 vaccination on the understanding that the main benefits from vaccination are related to the potential for indirect protection of their household contact who is immunosuppressed. • Please see section above 'Please confirm your age?' for further details regarding vaccination of children and young people. **Immunological response may be diminished in immunosuppressed patients, due to disease or immunosuppressive treatment, but it is important to immunise this group as they are considered high risk:** • Individuals who have immunosuppression and HIV infection (regardless of CD4 count) should be given COVID-19 vaccine in accordance with the recommendations and contraindications. • Emerging evidence suggests that many patients with immunosuppression are protected after two doses of vaccination. However, some individuals with more severe immunosuppression do not make a good immune response to a complete course of vaccine and may therefore remain at high risk. ○ Post-vaccination testing for spike antibody may be considered by specialists managing individuals with severe immunosuppression.

Question	Supporting information if Red Flag answer given

	• Advice should be sought from the relevant specialist for individuals due to or currently receiving chemotherapy, radiotherapy, targeted therapy, stem cell transplant or immunotherapy.
	
	Patients being treated with immunosuppressive chemotherapy:
	• The UK Chemotherapy Board Organisations recommended that all patients receiving systematic anti-cancer therapy (SACT) should be considered for vaccination. See also the UK Chemotherapy Board Clinician FAQs and guidance on COVID-19 vaccine for patients receiving Systemic Anti-Cancer Therapy.
	• If relevant, administration should be timed to coincide with when blood counts have maximally recovered but avoided on same day as chemotherapy.
	• Thrombocytopenia may be a minor consideration due to the need for an intramuscular injection – a platelet count of >20×10^9/L is preferable.
	• Vaccination should be delayed in patients with neutropenia who are unwell until the neutrophil count has recovered to >1 x10^9 /L and are well again. Patients with chronic neutropenia should be vaccinated without delay.
	• Medicines such as BCG, mitomycin, gemcitabine given by bladder instillation do not impact on timing of vaccination.
	• For rituximab:
	  ○ As monotherapy, there are no issues in relation to timing of vaccination provided blood counts are within acceptable range.
	  ○ In combination with cytotoxic chemotherapy, vaccine administration should coincide with maximal recovery of blood counts but avoided on same day as chemotherapy.
	
	Patients being treated with corticosteroids (oral, intra-articular, intra-muscular or intravenous):
	The British Society of Rheumatology and Arthritis and Musculoskeletal Alliance (ARMA) recommend the following but in each case the benefits and risks should be discussed with the patient to arrive at a shared decision:
	It is safe to have the COVID-19 vaccine alongside steroid exposure, but the patient may not mount such a good immune response.
	Do not delay vaccination for someone who is taking, has received or is soon to receive steroids in any form.
	If additional steroids are required to control inflammatory disease, that may take priority, as a flare can also worsen the risk from COVID-19
	• It may be appropriate to delay a non-essential steroid injection, as part of a shared decision, so that the response to the vaccine is more effective. For a patient who is on an elective waiting list for a steroid injection of up to 80mg methylprednisolone or 80mg triamcinolone, the administration of the COVID-19 vaccine is the priority if the vaccine has been offered to the patient and the prevalence of COVID-19 is high. In this scenario, the steroid injection should be deferred until 2 weeks after the vaccine, to enable the patient to mount the best response to the COVID-19 vaccine.
	
	Rheumatology patients receiving rituximab:
	• The British Society for Rheumatology advise:
	  ○ Where clinically possible, the COVID-19 vaccine course should be given four weeks or more before rituximab
	  ○ There may be a sub-optimal response to COVID-19 vaccines, especially for people within six months of the last dose of rituximab, or those who must have maintenance treatment due to their underlying clinical condition. BSR acknowledge that there is no evidence to suggest how long after rituximab a patient should delay vaccination with a COVID-19 vaccine, but consensus suggests this should ideally be 4-8 weeks after rituximab if it is ok to defer a COVID-19 vaccine. However, this may be dependent on the prevalence of COVID and should be agreed as being acceptable with the patient
	  ○ Where clinically appropriate, consideration should be given to using alternative therapies to rituximab, because of the potential that after rituximab there may be sub-optimal response to a COVID-19 vaccine. This should be on a case-by-case basis, balancing the need for rituximab and the suitability of alternative therapies for the relevant clinical situation.
	
	Patients with multiple sclerosis:

Question	Supporting information if Red Flag answer given
	The Multiple Sclerosis (MS) Society Medical Advisers have issued a consensus statement on COVID-19 vaccine for patients receiving MS treatments. Please refer to this for full details.
Peri-operative period?	**Recent or imminent elective surgery is NOT a contraindication to immunisation. However, if the patient has undergone surgery or surgery is planned within 7 days, separating the date of surgery from vaccination by a few days (at most 1 week) should be considered after:** • **individual assessment of both the patient and the type of surgery and** • **the risk to the individual of not being immunised** **Rationale for this advice:** • If patients undergoing surgery develop a temperature or a raised inflammatory profile in response to vaccination this can confuse the clinical picture and lead to issues in safe patient management. • With Comirnaty® vaccines, fever is more common after the second dose (15%) than the first dose (rare) and is more common in those aged <55 than in those aged >55. It mainly occurs in the first 1-2 days and is all gone by day 7. • With the Vaxzevria® (AstraZeneca) vaccine, post dose fever is considered to be a common adverse reaction (≥1/100 to <1/10). Adverse reactions reported after the second dose were milder and reported less frequently. Adverse reactions were generally milder and reported less frequently in those ≥65 years. • With the Spikevax® (Moderna) vaccine, fever was only seen after dose 2 and was classed as a very common adverse drug reaction. Both local and systemic reactions were less common in older trial participants. • The Green Book does not advise postponing surgery due to immunisation or vice versa. **Notes:** Essential urgent surgery should take place, irrespective of vaccination status.
Other Supporting Clinical Information	**Bone Marrow Transplant** – Individuals who receive a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations and for COVID-19 when treatment is finished. Specialist advice may be required. **Note:** Revaccination is not covered by the COVID-19 vaccine PGDs or NP and a PSD would be required. In addition, it is recommended that individuals with severe immunosuppression at the time of first or second primary COVID-19 vaccination should be offered a third primary dose of vaccine (see section below Third Primary Dose). **Breast Screening (impact of Axillary Swelling) –** UKHSA have confirmed that the scheduling of mammograms is not impacted by COVID-19 vaccination and there is currently **no requirement** for women to be advised to wait following a COVID-19 vaccination, before attending a screening appointment. Reports in the UK press refer to the risk of enlarged lymph nodes following COVID-19 vaccination which may cause unnecessary concern if mammograms are undertaken in close proximity to COVID-19 vaccination. For Comirnaty® vaccines (1st and 2nd dose) and Vaxzevria® (AstraZeneca) the risk of this is very low (frequency from trials is estimated to be less than 1%). However, for third doses of Comirnaty® vaccines a higher frequency of lymphadenopathy was observed (frequency 5.2%). For Spikevax® (Moderna), axillary swelling/tenderness is reported as 19.8% with a higher incidence in younger age groups (12-17 year olds, 35%). **Capillary Leak Syndrome** • **Vaxzevria® (AstraZeneca) vaccine** is contraindicated in individuals who have previously experienced episodes of capillary leak syndrome (CLS). **These individuals must be vaccinated with an alternative COVID-19 vaccine.** Extremely rare cases of this syndrome have been reported after Vaxzevria® (AstraZeneca) vaccine in individuals with a prior history. • **Spikevax® (Moderna) vaccine** SPC includes the caution that a few cases of CLS flare-ups have been reported in the first days after vaccination. Healthcare professionals should be aware of signs and symptoms of CLS to promptly recognise and treat the condition. In individuals with a medical history of CLS, planning of vaccination should be made in collaboration with appropriate medical experts.

Question	Supporting information if Red Flag answer given
	Efficacy of vaccine in doubt – if any part of vaccine management (including storage, handling, transportation, administration) breaches guidance or standard operating procedures in such a way as to bring vaccine efficacy in to doubt then further advice should be sought from the regional Clinical Advice and Response Service (CARS) as re-vaccination maybe required. Details on how to contact the service and report the incident can be found in the local COVID-19 Vaccination Safety Improvement and Learning SOP. Note: The PGDs and National Protocols for Comirnaty® and Vaxzevria® vaccines include in the 'off label' section advice that where vaccine that has deviated from the SmPC conditions of storage it should be assessed in line with UKHSA Vaccine Incident Guidance. If it is then deemed appropriate for continued use clinicians should be aware that this constitutes 'off-label' administration under the PGD or National Protocol. **Headache (persistent) post vaccination** – for further information see HWICS Clinical Guidance Notice: Blood Clotting, Headache and COVID-19 Vaccination. **Guillain-Barre syndrome (GBS)** – Very rare reports have been received of GBS following COVID-19 vaccination. Individuals who have a history of GBS should be vaccinated as recommended for their age and underlying risk status. Cases of GBS that occur following vaccination may occur by chance (the rate of GBS is 2 per 100,000 per year in the population); no causal mechanism with COVID-19 vaccination has been proven. There is evidence to suggest that having had a prior diagnosis of GBS does not predispose an individual to further episodes of GBS when immunised with other vaccines including Comirnaty® vaccines. In those who are diagnosed with GBS after the first dose of vaccine, the balance of risk benefit is in favour of completing a full COVID-19 vaccination schedule. On a precautionary basis, however, where GBS occurs within six weeks of an Vaxzevria® (AstraZeneca) vaccine, for any future dose mRNA vaccines are preferred. Where GBS occurs following either of the mRNA vaccines, further vaccination can proceed as normal, once recovered. **Notes:** 1. GBS has been reported very rarely within 6 weeks of Vaxzevria® (AstraZeneca) vaccine and rates appear to be higher than the background rates. 2. A warning has been added to the Vaxzevria® Summary of Product Characteristics which states: "Healthcare professionals should be alert of GBS signs and symptoms to ensure correct diagnosis, in order to initiate adequate supportive care and treatment, and to rule out other causes". Further information is available in Information for healthcare professionals on GBS following COVID-19 vaccination. **Inadvertent vaccine administration errors –** see section 2. **Lymphoedema** – vaccination is considered safe, but for individuals with upper limb swelling or at risk of developing upper limb lymphoedema, it is recommended that injections should be in the unaffected arm. If both arms are affected or at risk, it is recommended that both injections should be in the thigh. If all limbs are affected specialist advice should be sought. **Menstrual Disorders and Unexpected Vaginal Bleeding –** despite reports following vaccination, the relative number of reports are low and a link is not currently supported. The menstrual changes reported are mostly transient in nature and there is no evidence to suggest that COVID-19 vaccines will affect fertility and the ability to have children. Anyone experiencing changes to their periods that are unusual for them, persist over time, or any new vaginal bleeding after the menopause, following COVID-19 vaccination, should be advised to contact their doctor and should be treated according to clinical guidelines for these conditions, as usual. **Morbidly obese individuals** – 23g x 38mm needles are recommended for morbidly obese individuals; it is important to change the needle supplied with the administration syringe before the dose is drawn into the syringe to ensure that a full dose is administered. **Myocarditis and Pericarditis –** for further information on management of individuals (adult and paediatric) who develop myocarditis or pericarditis following COVID-19 vaccination please see HWICS Clinical Guidance Notice: Myocarditis and Pericarditis and COVID-19 Vaccination. **Multiple vaccinations –** Where two or more injections need to be administered at the same time, they should be given at separate sites (see below), preferably in a different

Question	Supporting information if Red Flag answer given
	limb. If more than one injection is to be given in the same limb, they should be administered at least 2.5cm apart. The site at which each injection is given should be noted in the individual's records. **Paediatric multisystem inflammatory syndrome temporally associated with COVID-19 (PIMS-TS) –** For children and young people who developed PIMS-TS in association with COVID-19 infection and then become eligible for vaccination, current advice suggests that an interval of three months should be observed, although earlier administration can be considered in those at risk of infection and/or who are fully recovered. **Porphyria** – vaccination is considered safe for use in patients with acute disease. **Prior allergy or current dietary practices** (including vaccine excipients and food content). **Site of COVID-19 vaccine injection –** The preferred site for intramuscular injection is the deltoid region. However, the injection may also be administered into the anterolateral thigh. This may be a consideration for people with limited/no muscle mass in their upper arms. **Transverse Myelitis** – Extremely rare cases of transverse myelitis have been reported following Vaxzevria®. The Vaxzevria® SPC states that a further dose of Vaxzevria® should not be given to those who have experienced symptoms of transverse myelitis after a previous dose of this vaccine.
Counselling (vaccine purpose, side effects, protective effect)?	**Protection:** • As with all vaccines, immunisation may not result in protection in all individuals. • Vaccine protection is not immediate and precautions against infection will need to be continued. • Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Guidance for people previously considered clinically extremely vulnerable from COVID-19 was updated on the 28th September 2021. • Nationally recommended protective measures should still be followed. **Individuals/carers advice should include:** • Possible **side effects** and their management – provide advice leaflet What to expect after your COVID-19 vaccination, which covers the reporting of adverse reactions and their management, such as with analgesic and/or antipyretic medication. • Signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any adverse symptoms. Advice leaflet Waiting after your COVID-19 vaccination is available. • Information regarding blood clotting following COVID-19 vaccination including advice to seek urgent medical advice if they experience any of the following symptoms more than 4 days after and within 30 days of COVID-19 vaccination: o new onset of severe headache, which is getting worse and does not respond to simple painkillers o 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, confusion, drowsiness or seizures o new unexplained pinprick bruising or bleeding o shortness of breath, chest pain, leg swelling or persistent abdominal pain See previous section "Major venous and/or arterial thrombosis with thrombo-cytopenia including Heparin Induced Thrombo-cytopenia (HITT or HIT type 2)" for more detail. • **Myocarditis and pericarditis** – very rare reports after vaccination with mRNA vaccines, often in younger men, shortly after the second dose of the vaccine. Cases are mild and individuals tend to recover within a short time following standard treatment and rest. Vaccinated individuals should seek immediate medical attention should they experience new onset of chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart within 2 weeks of a COVID-9 vaccination. See HWICS Clinical Guidance Notice: Myocarditis and Pericarditis and COVID-19 Vaccination for more detail. • Due to the risk of syncope following any vaccination, all patients receiving a vaccination should not drive for 15 minutes after vaccination or operate machinery. Housebound patients being vaccinated should be encouraged to have a relative/carer present where possible.

Question	Supporting information if Red Flag answer given
	• Individuals who experienced severe expected reactions after their first dose and are to receive a different vaccine for their 2nd primary dose, should be informed about the higher rate of such reactions following a 2nd dose of an alternate vaccine. • Occurrence of **mild post-immunisation fever**, which usually resolves within 48 hours. This is a common, expected reaction and isolation is not required unless COVID-19 is suspected. ○ Individuals should isolate and arrange to have a test if symptoms persist for longer than two days. • Reporting **suspected adverse reactions** using the Coronavirus Yellow Card reporting scheme, or search for MHRA Yellow Card in the Google Play or Apple App Store. • Seeking healthcare professional **advice** in the event of an adverse reaction. • Advising about when to return for vaccination/when a subsequent dose is due. • For all women of childbearing age refer to previous section on Pregnancy for COVID-19 vaccination in pregnancy: vaccinator checklist and additional counselling information. • Provide all women of childbearing age with the advice in the leaflet UKHSA COVID-19 vaccination: a guide on pregnancy and breastfeeding and checking their understanding as part of the consent process. • The British Fertility Society and Association of Reproductive and Clinical Scientists have produced a document addressing questions asked about COVID-19 vaccines and fertility. This states that there is absolutely no evidence, and no theoretical reason that any of the vaccines can affect the fertility of women or men. • The Lowdown on the COVID-19 Vaccine, Periods and Fertility – a patient friendly resource created in partnership with the NHS. • Information about COVID-19 vaccination should be made available ahead of the immunisation appointment for secondary school aged children and their parents: COVID-19 vaccination: resources for children and young people **Adverse reactions** – Detailed lists are available in the regulatory approvals for Vaxzevria® (AstraZeneca) vaccine, and in the Summary of Product Characteristics for Comirnaty® (10 micrograms/dose) for Children 5 to 11 years, Comirnaty® (30 micrograms/dose) for Adults and Adolescents and Spikevax® (Moderna). **Written patient information** – Ensure adequate information has been provided such as: • Vaxzevria® (AstraZeneca) vaccine Patient Information Leaflet • Spikevax® (Moderna) vaccine Package leaflet: Information for the user • Comirnaty® (30 micrograms/dose) for Adults and Adolescents Patient Information Leaflet • Comirnaty® (10 micrograms/dose) for Children 5 to 11 years Patient Information Leaflet • COVID-19 Vaccination Record Card (Product code: COV2020311) • What to expect after your COVID-19 vaccination (Product code: COV2020307) • Waiting after your COVID-19 vaccination (Product code: C21AAEN) • COVID-19 vaccination – a guide for children and young people (Product code: COV2021ERCU18) • COVID-19 vaccination – A guide for parent of children aged 5 to 11 • COVID-19 vaccinations: A guide for parents of children aged 5-11 years of age at high risk (Product code: C21CFE1OEN) • What to expect after your child's COVID vaccination – A guide for parents of children aged 5 to 11 years of age (Product code: C22W511EN) • COVID-19 vaccination: a guide for women of childbearing age, pregnant, planning a pregnancy or breastfeeding (Product code COV2020374V2) • COVID-19 vaccine – Your guide to booster vaccination • COVID-19 vaccine – A guide to the spring booster • COVID-19 vaccine – For people with a weakened immune system • A complete collection of patient leaflets is available here. **If vaccination is declined:** • Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.

Question	Supporting information if Red Flag answer given
	• Document advice given and the decision reached.
Consent and Marketing Authorisation	**Gaining and Documenting Consent for Vaccination:** **No written consent is required for those who have capacity and the recording of confirmation of verbal consent is sufficient**. The consent discussion must include any risks associated with the vaccine including common and rare side effects. It is advisable and good practice to document a consent discussion where the risk/ benefit judgement requires more complex considerations. Information about COVID-19 vaccination should be made available ahead of the immunisation appointment for secondary school aged children and their parents. UKHSA have published a range of information leaflets and consent documents that may be used if providers wish to obtain the vaccinee signature, remaining mindful of the balance of risks of creating additional paper records, including information governance and infection prevention and control. **Where a person lacks capacity, clear documentation must be in place** to evidence that either: • A **Lasting Power of Attorney** (Health and Welfare) has been consulted to provide or withhold consent • **A decision has been made to give or withhold the vaccine in the best interests of the person** Administration of the COVID-19 vaccine without verbally establishing informed consent, or in the absence of a documented best interest decision, is a breach of expected good practice and is a reportable incident. Consent forms, leaflets and letters to support the review and documentation of decisions are available from UKHSA. Additional guidance and resource links are available in the Green Book, Chapter 2 'Consent', which includes advice for gaining and documenting consent for vaccinating those who lack capacity, young people, those under 16 years of age who may be Gillick competent and for children. **Consent for use of Vaxzevria® (AstraZeneca) in patients under 40 years with no additional risk factors for COVID-19**: • If, in the **absence of a suitable alternative*,** following a conversation with a clinician, the risk vs benefit of immediate vaccination with Vaxzevria® (AstraZeneca) vaccine is **clinically** favourable, vaccination can proceed. However, it is essential that informed consent is given and carefully documented. Healthcare professionals should document that a full conversation has been had with the patient and they have been provided with sufficient information for them to give informed consent to vaccination. *This is defined as availability across the counties of Herefordshire and Worcestershire and does not apply to individual sites. ○ For further details see section above: Major venous and/or arterial thrombosis with thrombocytopenia including Heparin Induced Thrombocytopenia (HITT/HIT type 2) **Marketing Authorisation** As part of the consent process, healthcare professionals must inform the individual/carer the following as appropriate: **Vaxzevria® (AstraZeneca) vaccine** now has conditional marketing authorisation (CMA), (Regulatory approval of Vaxzevria® and COVID-19 Vaccine AstraZeneca) **First and Second Doses** ○ Authorisation is for individuals 18 years of age and older when administered as a two dose course, with the second dose being administered between 4 and 12 weeks after the first dose. ○ For Vaxzevria® a primary course using two different vaccine brands would be off label (but 'off label' use is supported by national guidance). **Third Primary and Booster** ○ Vaxzevria® authorisation (SPC) states a booster dose (third dose) may be given to individuals who previously received a 2 dose primary vaccination course with Vaxzevria. The third dose may be administered at least 6 months after completing the primary vaccination course. The decision when and for whom to implement a third dose of Vaxzevria should be made based on available vaccine effectiveness

Question	Supporting information if Red Flag answer given
	data, taking into account limited safety data. Therefore, booster doses at 3 months are off label (but 'off label' use is supported by national guidance). **Comirnaty® (30 micrograms/dose) for Adults and Adolescents** has a conditional marketing authorisation (CMA), (Summary of Product Characteristics Comirnaty® 30micrograms/dose): **First and Second Doses** ○ It is recommended to administer the second dose 3 weeks after the first dose; this means that administration beyond 3 weeks constitutes "off-label" use. ○ A primary course using two different vaccine brands would be off label (but 'off label' use is supported by national guidance). **Third Primary and Booster Doses** ○ For severely immunocompromised people aged 12 years and older, a third primary dose may be given at least 28 days after the second dose. ○ A booster dose of Comirnaty® may be administered at least 6 months after the second dose **in individuals 12 years of age and older;** therefore, early boosters remain off label (but 'off label' use is supported by national guidance). **Allergy** ○ Close observation for at least 15 minutes is recommended following vaccination. Therefore, suspension of the 15 min observation period would be considered, to be off label, (but 'off label' use is supported by national guidance). **Comirnaty® (10 micrograms/dose) for Children 5 to 11 years vaccine** has a conditional marketing authorisation (CMA) (Summary of Product Characteristics Comirnaty® 10 micrograms/dose): **First and Second Doses** ○ Authorised for individuals 5 to 11 years of age. It recommends administration of the second dose 3 weeks after the first dose; this means that administration beyond 3 weeks, in accordance with national policy, constitutes "off-label" use. ○ A primary course using two different vaccine brands would be off label (but 'off label' may be supported by national guidance if clinically appropriate). **Third Primary and Booster Doses** ○ Authorised for severely immunocompromised people aged 5 years and older, a third dose may be given at least 28 days after the second dose to individuals who are severely immunocompromised. ○ Booster doses are not included in the SPC **Allergy** ○ Close observation for at least 15 minutes is recommended following vaccination. Therefore, suspension of the 15 min observation period would be considered to be off label, (but 'off label' use is supported by national guidance). **Spikevax® (Moderna) vaccine** has a conditional marketing authorisation (Summary of Product Characteristics Spikevax®). **First and Second Doses** ○ For individuals 6 years of age and older, administered as a two dose course (dose dependent on age), with the second dose administered 28 days after the first. Where the second dose is administered beyond 4 weeks, or a primary course using two different vaccine brands is administered, use would be considered off label (but 'off label' use is supported by national guidance). **Third Primary** ○ For individuals 6 years and older a third dose (dose dependent on age) may be given at least 28 days after the second dose to individuals who are severely immunocompromised **Booster Doses** ○ For individuals 18 years of age and older, a booster dose (50 micrograms, half the primary dose) may be administered at least 3 months after the second dose; therefore boosters in under 18yrs remain off label (but 'off label' use is supported by MHRA statement) **Allergy** ○ The SPC states 'close observation for at least 15 minutes is recommended following vaccination'. Therefore, suspension of the 15 min observation period would be considered off label (but 'off label' use is supported by national guidance).

Question	Supporting information if Red Flag answer given
	Note: • Use outside of the conditional marketing authorisation is considered 'off label', however it maybe in accordance with national guidance.

Observation	**Suspension of 15min Wait Following Vaccination with a mRNA Vaccine**
	• On the 5th May 2022 the MHRA and the Commission on Human Medicines formally removed the 15-minute observation period following vaccination with a mRNA vaccine for individuals aged 12 years and over without a history of allergy (as outlined in the Green Book.)
	• A temporary suspension of the 15-minute observation period for children aged 5-11 years remains in place (this will be reviewed on a regular basis).
	• Following vaccination with all COVID-19 vaccines individuals should be:
	  ○ Observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre
	  ○ Informed of signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms. Advice leaflet Waiting after your COVID-19 vaccination is available.
	• In some settings, for example domiciliary vaccination, it may be appropriate for a responsible adult to be present for at least 15 minutes after vaccination.
	• No specific management is required for patients with a family history of allergies.
	• See the Allergy section of this document for additional observation requirements for people with a history of allergy.
	• Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting. **Observation for 15 minutes is recommended.**
	• As fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should not drive for 15 minutes after vaccination.
	• Incidents occurring should follow the Vaccination Incident Management SOP
	• Document any adverse reactions in the individual's record and inform individual's GP.
	• Report via the Coronavirus Yellow Card reporting scheme
	• The Green Book Chapter 14a and Chapter 8 provide further details regarding the clinical features of reactions to be reported as 'anaphylaxis'. Allergic reactions that do not include the clinical features of anaphylaxis should be reported as 'allergic reaction'.

Second Dose Scheduling	**Section 1: COVID-19 Vaccine: Dose Schedule Summary** provides a quick reference guide to dosing schedules for all eligible age cohorts. **JCVI recommends a minimum interval of eight weeks between doses of all the available COVID-19 vaccines where a two-dose primary schedule is used for adults and for children and young people in a risk group (cohorts 1, 2, 4 and 6).** • **Young people aged 5 to 17 years, not in a risk group (cohorts 1, 2, 4 and 6)**, should be offered a second dose of age appropriate Comirnaty® vaccine at 12 weeks or more following the first vaccine dose. • For individuals in a risk group (cohorts 1, 2, 4 and 6) and all those 18 years and over, second dose vaccinations should not be offered earlier than eight weeks. • For information on management of individuals with history of recent COVID-19 infection see section above Recent COVID symptoms, asymptomatic with COVID positive PCR test result or currently required to self-isolate? • For both adenovirus vector and mRNA vaccines, there is evidence of better immune response and/or protection where longer intervals between doses are used. • In advance of commencing immunosuppressive interventions, the Green Book advises that the second vaccination may be administered at the recommended minimum interval for that vaccine or as soon as possible (see Immunocompromised or Receiving Immunosuppressive Therapy section above). • All PGDs and NPs for available COVID-19 vaccines cover the administration of the second dose at any interval beyond the vaccine specific minimum required. (Vaxzevria® (AstraZeneca) 28 days, Spikevax® (Moderna) 28 days, Comirnaty® vaccines 21 days). • See 'Consent and Marketing Authorisation' section above for details regarding 'off label' use. **Points to consider for 2nd doses:**

Question	Supporting information if Red Flag answer given

	• **Children aged 12 years in school year 7**
	  ○ Further national operational guidance will be provided to support vaccination of 12 year olds in school year 7 with Comirnaty® (10 micrograms/dose) for Children 5 to 11 years. This change is not expected to be implemented until late April 2022.
	• The NP and PGD for Comirnaty® 10micrograms/dose for Children 5 to 11 years may be used for individuals aged:
	  ○ 5 to 11 years, not in a risk group (one-off programme)
	  ○ 5-11 years in a risk group
	  ○ 12 years and in school year 7
	  ○ 12 years who commenced, but did not complete a primary course, with Comirnaty® (10 micrograms/dose) for children 5 to 11 years
	  ○ 12 years who commenced, but did not complete a primary course, with a fractional 10 microgram dose of Comirnaty® (30 micrograms/dose) for adults and adolescents
	• Evidence suggests that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines make a good immune response, although rates of side effects with a heterologous second dose are higher.
	• Accumulating evidence supports the use of heterologous schedules for primary immunisation.
	• **For individuals, over 18 years, who started the schedule and who attend for vaccination where the same vaccine is not available or suitable, or if the first product received is unknown or not available, one dose of the locally available product should be given to complete the primary course.** This is covered by current PGDs and NPs for all available vaccines.
	• Young people aged 16-17 years who received a first dose of Vaxzevria® (AstraZeneca) may complete with the same vaccine or with Comirnaty® (30 micrograms/dose) for Adults and Adolescents.
	• Individuals who experienced severe expected reactions after a first dose of Vaxzevria® (AstraZeneca) or mRNA vaccines should be informed about the higher rate of such reactions when they receive a second dose of an alternate vaccine.
	• It is important that clinical assessment of individuals for second doses should be as thorough as for first doses and include questions regarding any adverse drug reactions following dose one.
	• Only individuals about to start an intervention that will result in them becoming high risk should have their second dose brought forward ahead of the National Policy schedule.
	• NHSE COVID-19 vaccination programme: FAQs on second doses provides further information.

Third Primary Dose	**Section 1: COVID-19 Vaccine: Dose Schedule Summary** provides a quick reference guide to dosing schedules for all eligible age cohorts. HWICS Action Notice: Arrangements for Access to a Third Primary COVID-19 Vaccine Dose provides details of the local arrangements for identifying and vaccinating local patients. JCVI advises that a third vaccine dose be offered to individuals aged 5 years and over who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule. Criteria for a third dose of COVID-19 vaccine are available in the Green Book Chapter 14a (Box 1 for those aged 12 years and above, Box 2 for children 5-11 years) more operational guidance is available in the local action notice. **Vaccine Choice for Third Primary Dose:** 1. **Young people aged 5 to 17 years** should be offered a dose of age appropriate Comirnaty® vaccine 2. **For those aged 18 years and over** – mRNA vaccines (Comirnaty® (30 micrograms/dose) for Adults and Adolescents or Spikevax® (Moderna)) are preferred. Vaxzevria® (AstraZeneca) vaccine can be considered for individuals who have received this vaccine previously where this would facilitate delivery. In exceptional circumstances, persons who received a mRNA COVID-19 vaccine previously may be offered a third primary dose of Vaxzevria® (AstraZeneca) vaccine, but only following a decision by a health professional on a case-by-case, individualised basis, taking in to account relevant contraindications and cautions. **Third Dose Timing Schedule:**

Question	Supporting information if Red Flag answer given
	The third primary dose should ideally be given at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies guided by the following principles: 1. Where possible, the third primary dose should be delayed until 2 weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent 2. If not possible, consideration should be given to vaccination during a treatment 'holiday' or when the degree of immunosuppression is at a minimum. Advice for patients on chemotherapy is available from the UK Chemotherapy Board. **Notes:** • Most individuals whose immunosuppression commenced at least two weeks after the second dose of vaccination do not require an additional primary vaccination at this stage. Although specialist advice may need to be sought for the 5-11 years cohort. • The decision on the timing of the third dose should be undertaken by the specialist involved in the care of the patient. In general, vaccines administered during periods of minimum immunosuppression (where possible) are more likely to generate better immune responses. • Individuals who had received brief immunosuppression (12 years and older: ≤40mg prednisolone per day, 5-11 years: ≤2mg/kg prednisolone per day) for an acute episode (for example, asthma / COPD / COVID-19) and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination. • **The current PGDs and NPs for all available COVID-19 vaccines include third primary doses.** • **Children aged 12 years in school year 7** ○ Further national operational guidance will be provided to support vaccination of 12 year olds in school year 7 with Comirnaty® (10 micrograms/dose) for Children 5 to 11 years. This change is not expected to be implemented until late April 2022. • See 'Consent and Marketing Authorisation' section above for details regarding 'off label' use. • It is important that clinical assessment of individuals for third primary doses should be as thorough as for earlier doses and include questions regarding any adverse drug reactions following previous doses.
Booster Vaccine Programme including Spring 2022 Campaign	**Section 1: COVID-19 Vaccine: Dose Schedule Summary** provides a quick reference guide to dosing schedules for all eligible age cohorts. **Vaccine Choice for Booster Dose:** • **Children and young people aged 12 to 17 years** - Should be offered a booster dose of Comirnaty® (30 micrograms/dose) for Adults and Adolescents. • **Adults 18 years and over –** Comirnaty® (30 micrograms/dose) for Adults and Adolescents or a half dose (50micrograms) of the Spikevax® (Moderna) vaccine should be offered as a booster dose irrespective of which product was used in the primary schedule. **Notes:** • **Children aged 12 years in school year 7** ○ Further national operational guidance will be provided to support vaccination of 12 year olds in school year 7 with Comirnaty® (10 micrograms/dose) for Children 5 to 11 years. This change is not expected to be implemented until late April 2022. • Where mRNA vaccines are clinically contraindicated Vaxzevria® (AstraZeneca) vaccine may be considered for those who received at least one dose of this vaccine previously. • In exceptional circumstances, persons aged 40 years or over who received a mRNA COVID-19 vaccine previously may be offered a booster dose of Vaxzevria® (AstraZeneca) vaccine following a decision by a health professional on a case-by case basis. **Spring Booster Campaign 2022 – Delivery from 21st March 2022** The following cohorts are eligible for a booster dose irrespective of how many doses they have previously received: • adults aged 75 years and over • residents in a care home for older adults,

Question	Supporting information if Red Flag answer given

	• individuals aged 12 years and over who are immunosuppressed (as defined in the Green Book tables 3 or 4)
	
	Timing of Spring Booster Vaccination:
	• Vaccination should ideally be offered around six months from any previous dose.
	• Operational flexibility may be used to maximise uptake **providing there is at least three months from the previous dose.**
	  ○ Individuals in care homes or housebound patients may be offered a booster alongside other residents.
	  ○ All eligible people should be offered a booster during the spring campaign providing there is at least three months from the previous dose.
	  ○ An additional dose is not then recommended before the autumn.
	
	Notes:
	• Pregnancy (all stages) is now considered a clinical risk factor for severe COVID-19 infection. All pregnant women should now be offered COVID-19 vaccination in line with clinical and other risk groups, this includes booster vaccinations.
	• **The current PGDs and NPs for Comirnaty® (30 micrograms/dose) for Adults and Adolescents, Vaxzevria® and Spikevax® (Moderna) vaccines include booster vaccination at a minimum interval of three months from the previous dose (this includes those individuals who have received a three dose primary course).**
	Note:
	  ○ PGDs and NPs can be used to vaccinate from 12 weeks (84 days).
	  ○ The Vaxzevria® vaccine PGD and NP include boosters only where mRNA vaccines are clinically contra-indicated, and the individual has received at least one dose of an AstraZeneca COVID-19 vaccine previously.
	• See 'Consent and Marketing Authorisation' section above for details regarding 'off label' use.
	• It is important that clinical assessment of individuals for booster doses should be as thorough as for earlier doses and include questions regarding any adverse drug reactions following previous doses.
	• Information for eligible individuals is available from UKHSA COVID-19 vaccination: booster dose resources

3. COVID-19 VACCINATION PROGRAMME - Management of Inadvertent Vaccine Administration Errors

Inadvertent Administration Error	Recommended Action	Rationale
Whole multi-dose vial of vaccine	The person should be monitored and treated for any symptoms as required. They should be reassured that this is not harmful but that they may be more likely to experience pain in their injected arm. Any subsequent doses due should still be given as per the recommended schedule.	In a Phase I/II study of COVID-19 mRNA vaccine BNT162b1 in adults, different strength doses of the Pfizer-BioNTech vaccine were given. The trial showed that a stronger dose (100 micrograms instead of the recommended 30 microgram dose) was not harmful, but the recipients experienced more local reactions with very painful arms being reported. Participants who received 58 micrograms of COVID-19 mRNA vaccine in clinical trials did not report an increase in reactogenicity or adverse events. The Spikevax® (Moderna) vaccine has also been given at higher dose levels in clinical trials than the dose recommended in the UK vaccination programme.
Incomplete dose of vaccine	A risk assessment should be carried out to determine whether it is necessary to repeat the dose. If at least half of the full dose of an mRNA vaccine was administered, the immune response to a primary dose in healthy younger people or to a booster in any age group would be considered adequate except for those with immunosuppression (as defined in the Green Book). Where the risk of under-dosing is considered substantial, it is recommended that a full additional recommended dose should be given immediately. If the error is only realised after the patient leaves the vaccination clinic, it is recommended that the repeat dose should be offered from 48 hours to 7 days after the possible partial dose was given. If the dose is repeated, the recipient should be advised of possible side effects. Any subsequent doses due should still be given as per the recommended schedule.	Example of error - vaccine leakage as it is being administered. The 48 hour wait period is to allow for any reactions experienced following the incomplete dose to resolve before the repeat dose is given. It is recommended that the repeat dose should be given within 7 days of the incomplete dose to minimise the time the individual may be left susceptible to infection. If more than 7 days have elapsed, a further risk assessment will be required to decide on the optimal timing for a repeat dose, considering the individual risk and epidemiological context. Trial data for the Pfizer-BioNTech and Moderna vaccines showed a good immune response was made to a lower dose of the vaccine than the recommended authorised dose, particularly in younger age groups and as a booster. For Pfizer-BioNTech, a third of the adult dose was as immunogenic in children aged 5-11 years as a full adult dose in those aged 16 to 25 years. A half dose of Pfizer-BioNTech vaccine also produced a similar antibody boost as a full dose when used as a booster in adults from a broad age range who had been primed with either AstraZeneca or Pfizer-BioNTech.

Inadvertent Administration Error	Recommended Action	Rationale
Comirnaty® (10micrograms/dose) for Children 5 to 11 years administered to an individual aged 12 years and over instead of recommended 30 microgram dose	If a young person aged 12 to 15 years is inadvertently given a dose of Comirnaty® (10 microgram/dose) for Children 5 to 11 years instead of the recommended Comirnaty® (30 microgram/dose) for Adults/Adolescents, this dose can still be counted as a valid dose and does not need to be repeated. Note: • JCVI have advised that those aged 12 years may commence or complete with a 10 microgram dose to align with their peers in the same academic year (where those aged 12 years are being vaccinated alongside those aged 11 years in a school-based COVID-19 vaccination programme). • This change is not expected to be implemented until late April 2022 and further national operational guidance will be provided prior to this.	If this was the first dose: • Children aged 12 years should complete their primary vaccination course with the 10 microgram dose (although the 30 microgram dose is an acceptable alternative if this is the only vaccine available. • Those aged 13 to 15 years should be given the 30 microgram dose for their second dose.
Vaccine potency may have been adversely affected by an inadvertent storage or preparation error	Seek expert advice. If expert advice recommends that the dose of vaccine be repeated, this should either be given on the same day as the potentially affected dose was given or, from 48 hours to 7 days after the potentially affected dose was given. If the dose is repeated, the recipient should be advised of possible side effects. Any subsequent doses due should still be given as per the recommended schedule. Where vaccine storage has deviated from the SmPC conditions of storage it should be assessed in line with UKHSA Vaccine Incident Guidance. If it is then deemed appropriate for continued use clinicians should be aware that this constitutes 'off-label' administration under the PGD or National Protocol.	Example of error - a storage or preparation error. The 48 hour wait period is to allow for any reactions experienced following the potentially affected dose to resolve before the replacement dose is given. It is recommended that the replacement dose should be given within 7 days of the potentially affected dose to minimise the time the individual may be left susceptible to infection. If more than 7 days have elapsed, a further risk assessment will be required to decide on the optimal timing for a repeat dose, considering the individual risk and epidemiological context.
Diluent only (for COVID-19 vaccines that require dilution)	The person should be given a dose of properly reconstituted Comirnaty® vaccine as soon as the error is realised.	The diluent alone will not evoke an immune response. The diluent for Comirnaty® vaccines is 0.9% sodium chloride, commonly used to dilute other medicines. No adverse reactions would be expected if it was inadvertently administered alone.
Over-diluted vaccine	A risk assessment should be carried out to establish what the likely concentration of the vaccine given was and the individual's age, whether they are immunosuppressed or have an underlying clinical risk condition, whether they have previously had confirmed COVID-19 infection and whether this is the first, second or booster dose. If the vaccine has been significantly over-diluted, the dose should be repeated as soon as the error is realised using a correctly reconstituted vaccine (or from 48 hours later if not repeated on the same day).	The amount of active content in a dose of over-diluted vaccine will be less than the recommended amount.
Vaccination of a young person less than 12 weeks after COVID-19 infection	Young people aged 12 to 17 years should be reassured but made aware that they may be more likely to have side effects. Most side effects are mild, start within hours of vaccination and resolve within a few days. Paracetamol can be used to manage symptoms.	Young people aged 12 to 17 years who have inadvertently received a COVID-19 vaccine less than 12 weeks after having COVID-19 infection can be reassured that they will produce an adequate immune response to the vaccine.

Inadvertent Administration Error	Recommended Action	Rationale
Second dose given at less than the minimum recommended interval	**Vaxzevria® (AstraZeneca) or Spikevax® (Moderna) vaccine** - if given at less than the recommended minimum 28 day interval, but at least 21 days after the first dose, it does not need to be repeated. If the second dose is given less than 21 days after the first, it should be discounted and another dose (a third dose) should be given at least 28 days after (standard interval 8-12 weeks after the dose given too early. **Comirnaty® vaccines** - If given less than 19 days after the first dose, the dose should be discounted and another dose (a third dose) should be given at least 21 days after the dose given too early.	**Comirnaty® vaccines** - The 19 day interval is the minimum interval that was used in the clinical trials.
Longer than maximum recommended interval between doses	The second dose should still be given. The course does not need to be restarted. Individuals should be encouraged to receive their second dose on time as this will significantly boost their protection and prevent further hospitalisations and deaths. Timely administration of the second dose is especially important when COVID-19 community infection rates are high or increasing, although deferral after COVID-19 infection is advised.	Data from clinical trials shows that the efficacy of the AstraZeneca vaccine was higher when the second dose was given at, or after 12 weeks, and a study of people aged over 80 years found that extending the second dose interval to 12 weeks for the Pfizer-BioNTech vaccine markedly increased the peak spike-specific antibody response by 3 and a half times compared to those who had their second vaccine at 3 weeks.
Different COVID-19 vaccine given for second primary dose than was given for first dose at correct interval	They should be informed that they may experience more side effects than they did following their first dose but that a further dose is not required.	Evidence from trials suggest that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines, make a good immune response, although rates of side effects at the second dose are higher. Reactogenicity and safety data from the Com-COV clinical trial showed that mixed schedule recipients were more likely to experience feverishness, chills, fatigue, headache, joint pain, malaise, and muscle ache.
Different COVID-19 vaccine given at a short interval after the first dose	If a dose of a different COVID-19 vaccine is inadvertently given a few days after the first dose was given, the person should be offered a third dose of vaccine at the currently recommended interval for second doses (8 weeks from when the second dose was given). If different COVID-19 vaccines are given a minimum of 21 days apart, these doses should be counted as a completed course and no further doses are needed.	
Half dose of Spikevax® (Moderna) vaccine given as third primary dose to an immunosuppressed individual	The dose does not need to be repeated as it is expected that a half dose will still produce a good immune response and is expected to be equivalent to that of a full dose of Comirnaty® (30 micrograms/dose) for Adults and Adolescents.	A study using a half dose of Moderna (50micrograms) in those who had received a primary course of Moderna (100micrograms) showed good immunogenicity and a rate of reactions similar to the second dose of Moderna.

Inadvertent Administration Error	Recommended Action	Rationale
Administration of a booster dose less than 3 months after the second dose	Where the booster dose is inadvertently given earlier than 3 months (12 weeks) from the final primary dose, it should not be counted as a valid booster dose and a further booster dose should be scheduled around 3 months from the dose inadvertently given early.	The JCVI recommend that booster vaccination should not be given within 3 months of completion of the primary course.

Note: Errors or incidents in vaccine storage, preparation or administration should be reported in accordance with NHS Herefordshire and Worcestershire System Vaccine Operations Centre COVID-19 Vaccination Safety Improvement and Learning SOP.

4. COVID-19 VACCINATION PROGRAMME – Frequently Asked Clinical Questions

	Question/Topic	Things to consider
CHANGE OF CIRCUMSTANCES/TIMING INTERVAL		
1.	Missed second dose appointment	Where second dose appointments are missed (e.g. due to hospital admission or positive COVID-19 test/symptoms) and the required vaccine is not available when the patient represents: • Vaccination should take place as soon as possible with a clinically appropriate vaccine. • There is no need to repeat the 1st dose if the 2nd second dose is administered beyond 12 weeks.
2.	COVID-19 vaccinations received overseas	UKHSA have published guidance regarding vaccination of those who received COVID-19 vaccine overseas. People over 16 who have had one or more COVID-19 vaccinations abroad that are approved by WHO can book an appointment at a vaccination site via the NHS website to show evidence of their vaccinations and request an update to their record General recommendations are as follows: • If a person has received a first dose of a COVID-19 vaccine overseas that is also available in the UK, they should receive the same vaccine for their second dose (unless contraindicated). • If the vaccine they received for their first dose is not available in the UK, the most similar alternative should be offered for the second dose (for details see full guidance). • If the vaccine received overseas is not listed, a full course of the appropriate vaccine recommended for the individual in the UK should be given. • Individuals eligible for third primary dose or booster doses should be vaccinated in line with national guidance. See sections 'Third Primary Dose' and 'Booster Vaccine Programme for winter 2021 to 2022' above. • There should be a minimum interval of 3 months between final primary dose and booster. For those considered fully vaccinated before arrival, the 3 months is taken from their final dose given overseas; for those requiring one or more UK doses, the 3 month interval is taken from the final 'additional' dose given in the UK. • There is no need to repeat the first dose if the second dose is administered beyond the recommended interval. • The Point of Care system at the vaccination site needs to be able to capture the administration and update the individual's clinical records. • Pinnacle Support have advised that it is possible to add the 2nd vaccination as normal. The system will show a warning, but it is possible to proceed. Include in the 'notes' field where and when the first vaccination took place. It is advised that the individual's general practice clinical record be updated with the oversees 1st vaccination to make sure it contains both vaccinations. • For support with facilitating vaccination in this situation please contact hw.medicines@nhs.net.
3.	COVID-19 vaccine clinical trialist – requesting revaccination	Vaccine clinical trial participants are being offered the option to get additional vaccine doses to ensure they can travel abroad to countries which currently only accept vaccination records for COVID-19 vaccines approved for deployment. Letters will be sent out by trial teams, to clinical trial participants, who are responsible for outlining further details and next steps and responding to any questions arising. **Notes:** • The UK recognises those who received two doses of COVID-19 vaccine, not placebo, as part of a clinical trial as fully vaccinated for the purpose of certification, both domestic and international. However, the majority of other countries currently do not and require visitors to have been fully vaccinated with a vaccine that has been approved for deployment by the relevant medicines regulator.

	Question/Topic	Things to consider
		• People who have received both doses of a vaccine as part of a clinical trial should also be offered a 3rd primary dose and/or booster dose if eligible, in line with Green Book advice (See sections 'Third Primary Dose' and 'Booster Vaccine Programme above). • If an individual is not sure what they have received - or have lost their letter from the trial/ manufacturer which states this - then they must contact their trial team for this information, and for advice. • Further national details are available here. • Please also see Previous or planned COVID-19 vaccine? section above for further details.
CHANGE IN HEALTH		

4.	Positive COVID-19 test result or symptoms prior to vaccination	The Green Book recommends the following:
		• There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical and epidemiological features to suggest the episode was COVID-19 infection.
		• For individuals who have had proven COVID-19 infection any subsequent COVID-19 vaccination should ideally be deferred until:
		  ○ twelve weeks from onset (or sample date) for those under 18 years of age who are not in a risk group (cohorts 1,2, 4 and 6)
		  Note: When advised via national operational letter, this interval may be reduced to eight weeks in healthy under 18 year olds when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population.
		  ○ four weeks from onset (or sample date) for individuals in a risk group (cohorts 1,2, 4 and 6) and all those over 18 years of age
		  Note: When advised via national operational letter, this interval may be reduced to ensure operational flexibility when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. In care home residents and the housebound, there may be advantage in offering vaccination to those with recent confirmed COVID-19, without a four-week deferral, where individuals are clinically stable and infection control procedures can be maintained. These populations are likely to be highly vulnerable and this will facilitate vaccination without the need for multiple visits.
		Notes:
		• **All COVID-19 vaccine PGDs and NPs allow for administration at shorter intervals when advised nationally.**
		• In younger people, protection from natural infection is likely to be high for a period of months, and vaccination in those recently infected may increase the chance of side effects.
		• COVID-19 symptoms or a requirement to isolate will exclude a person from attending a vaccination site.
		• Fever and being acutely unwell are contra-indications to vaccination.
		• For the majority of people vaccination should be deferred until 4 or 12 weeks (depending on cohort) clear of a positive test or onset of symptoms.
		• Vaccination in advance of the recommended 4 or 12 weeks should not be agreed for issues of convenience.
		• To minimise the risk of complaints regarding COVID-19 infection following vaccination site visit see HWICS Infection Prevention and Control (IPC) guidance for support.
		• CQC require all practices, including vaccination sites to adhere to IPC protocol.

	Question/Topic	Things to consider
5.	Short course of oral steroids (equivalent to prednisolone 40mg daily or less) being taken at the time of vaccine appointment.	There are some general principles but in each case the benefits and risks should be discussed with the patient to arrive at a shared decision: • It is safe to have the COVID-19 vaccine alongside steroid exposure, but the patient may not mount such a good immune response. • There is limited evidence regarding response in immunosuppressed individuals and optimal timing of vaccination. • Specialists may advise their patients based on their knowledge and understanding of their immune status and likely immune response to vaccination but should also consider the risk from COVID and the patient's likelihood of exposure. • Do not delay vaccination for someone who is taking, has received or is soon to receive steroids in any form. • If additional steroids are required to control inflammatory disease, that may take priority, as a flare can also worsen the risk from COVID-19 • It may be appropriate to delay a non-essential steroid injection, as part of a shared decision, so that the response to the vaccine is more effective. For a patient who is on an elective waiting list for a steroid injection of up to 80mg methylprednisolone or 80mg triamcinolone, the administration of the COVID-19 vaccine is the priority if the vaccine has been offered to the patient and the prevalence of COVID-19 is high. In this scenario, the steroid injection should be deferred by 2 weeks after the vaccine, to enable the patient to mount the best response to the COVID-19 vaccine.

6.	Gestational diabetes - risk factors	• Some people with previous gestational diabetes have been identified by the QCovid® model as being at high risk.
		• If a person has been identified as being at high risk due to previous gestational diabetes only (no other significant conditions) and both:
		  • has a Body Mass Index (BMI) between 16 and 41 and
		  • has had a HbA1c (a test to check average blood glucose/sugar levels) since delivery and within the last 12 months which is normal or in the pre-diabetes or non-diabetic hyperglycaemia range
		they do not need to be included in the Shielded Patient List (SPL) and can be removed if they request this.
		• They will still be called for an earlier vaccine.
		• Shielding (when advised nationally) is advisory and people who have received a letter can choose whether or not to shield.
		• Clinicians should always use their clinical judgement and discuss any decision to remove a patient from the SPL.

7.	An individual taking immunosuppressive medicine presents stating they are eligible for earlier vaccination. What actions are required?	A local pathway for early access to COVID-19 vaccination has been put in place. Patient eligibility should be determined by a consultant based on whether a planned intervention will result in a patient becoming high risk. GPs should only schedule early COVID-19 vaccination upon receipt of a completed template in accordance with the following action notice: • Action Notice: Arrangements for Early Access to COVID-19 Vaccination Pre-High Risk • HWICS Request for Early Access to COVID-19 Vaccination
8.	UKHSA Surveillance Programme – individuals who develop COVID-19 symptoms post vaccination.	• UK Health Security Agency Immunisation Department is conducting enhanced surveillance of cases of infection in vaccinated individuals in England. • Clinicians who are seeing patients face to face are also encouraged to report any confirmed cases in partially or fully vaccinated individuals if they tested positive within the preceding 7 days. • Further information is available via UKHSA Reporting to the enhanced surveillance of COVID-19 cases in vaccinated individuals , and cases can be reported using the Online form.

	Question/Topic	Things to consider
9.	Time interval between treatments for COVID-19 disease and vaccine administration	When an individual has received recent treatment for COVID-19 and presents for COVID-19 vaccination, the following should be considered: • As the currently authorised COVID-19 vaccines are non-live vaccines, it is not anticipated that these treatments would contraindicate the vaccine. Although theoretically, high levels of antibodies in the convalescent plasma could interfere with the immune response to the vaccine, passively acquired antibodies from the plasma treatment are not thought to persist for long so by the time a person who has received this is well enough to receive a COVID-19 vaccination, these antibodies are likely to have gone. • **Convalescent plasma** is a preparation of pooled antibodies taken from people who have recently recovered from COVID-19. The antibodies bind to the surface of the SARSCoV-2 virus and stop it from attaching to the body's cells and replicating further. This treatment may have a short-term impact on the effectiveness of the COVID-19 vaccine; therefore, patients are advised to delay vaccination until 3 months after treatment. • **Monoclonal antibody** treatment works in the same way as convalescent plasma but is a specific preparation containing 2 specific man-made antibodies. No specific interval is required between receipt of monoclonal antibodies used for the treatment or prophylaxis of COVID-19 infection and COVID-19 vaccination, or vice versa. • **Antivirals** prevent the further replication of viruses. As none of the currently authorised COVID-19 vaccines contain live replicating virus, response to the vaccine will not be affected by prior or recent receipt of anti-viral medication. Please see FAQ 12 (below) for further information regarding the RECOVERY Trial.
INCIDENTS		
10.	Inadvertent first dose vaccination of CYP with Vaxzevria® (AstraZeneca) COVID-19 vaccine.	If a dose of Vaxzevria® (AstraZeneca) is administered inadvertently to an individual less than 18 years of age: • This should be reported as an incident in line with the local HWICS COVID-19 Vaccination Incident Management SOP. • There is some (unpublished) data from clinical trials that ~~the~~ Vaxzevria® (AstraZeneca) vaccine is effective with those aged less than 18 yrs. • The Green Book guidance, supported by the JCVI gives preference for Comirnaty® vaccines in all individuals under 18 years of age. Young people (under 18 years) who have already received a dose of Vaxzevria® (AstraZeneca) vaccine can complete with the same vaccine or with Comirnaty® vaccines (unless contraindicated). • If a child or young person under 18 years attends an Vaxzevria® (AstraZeneca) clinic they should be reappointed to a Comirnaty® vaccines clinic rather than be offered Vaxzevria® (AstraZeneca). • Vaxzevria® (AstraZeneca) vaccine - is not authorised for use in patients less than 18 years old, and these patients are not covered by the PGD or NP. The vaccine must therefore be administered under a PSD. • Comirnaty® (30 micrograms/dose) for Adults and Adolescents - is not authorised for use in patients less than 12 years old. • Comirnaty® (10 micrograms/dose) for Children 5 to 11 years – is authorised for children aged 5 to 11 years. • Spikevax® (Moderna) vaccine – is not authorised for use in individuals less than 6 years old. Green Book advice remains that Comirnaty® vaccines should be offered to children and young people.

	Question/Topic	Things to consider
11.	Inadvertent COVID-19 vaccination within 3 months of RECOVERY Trial (treatment with convalescent plasma or antibodies)	Individuals who took part in the RECOVERY (Randomised Evaluation of COVID-19 Therapy) Trial whilst being treated for COVID-19 infection as hospital inpatients, will have been administered either synthetic antibodies or antibodies taken from convalescent plasma. These antibody treatments may have a short-term impact on the effectiveness of the COVID-19 vaccine; therefore, patients are advised to delay vaccination until 3 months after treatment. Provider Trusts should write to patients and GPs to inform them of this advice; however, it is possible that inadvertent vaccination may occur within the 3-month period. In cases such as this the following should be noted: • These patients will already have had confirmed COVID-19 infection in the past and therefore will have some natural immunity which is likely to have been boosted by the vaccine. • It is thought that the circulating antibodies from convalescent plasma last around six weeks, if inadvertent vaccination occurs after 5-6 weeks after receiving treatment it is likely that the antibodies would have waned considerably, and therefore would not have a significant impact on the efficacy of the vaccine. • For individual patient queries please contact regional Clinical Advice and Response Service (CARS) via the PMO email address: england.midscovid19vacs.pmo@nhs.net marked 'for the attention of CARS'.
SERVICE DELIVERY ISSUES		
12.	Pinnacle data errors - Individuals presenting for vaccination but data held on Pinnacle is incorrect.	The accuracy of data within Pinnacle and timeliness in the data transfers between systems into EMIS is still contributing toward significant events / incidents, including repeat vaccination within a short a timescale. **Managing Pinnacle Errors** • On occasions a PCN has reported where a patient presents for their first dose yet pinnacle suggests a first dose is already recorded against that name. • The Regional team have advised that where this occurs details should be sent to vaccineservicedesk@england.nhs.uk . The patient details can be searched across the system to find out where the first vaccination was recorded if it was in Outcomes4Health. Records will then be checked to establish if details have been recorded against the wrong patient, and where this is the case, the provision will be cancelled, and NIMS updated. **Additional points to consider:** • Clinicians are reminded to ensure that, in the event of a vaccination **not** being given, the reason for this is recorded on the system. Further details should also be recorded in the clinical notes box; note however that patient identifiable data should **not** be used as this information appears in audit reports. • Adverse reactions to the vaccine at the time of the vaccination event should also be captured in the 'Reactions' field. Again, further non-patient-identifiable information can be recorded in the clinical notes box. • Any issues or problems with Pinnacle functionality should be addressed to the Pinnacle Health helpdesk who can be messaged directly by clicking on the 'contact us' tab of the home screen. **Vaccine Data Resolution Service (VDRS)** • This service aims to resolve missing or incorrect vaccination records for individuals vaccinated in England who have a current NHS number and are registered with a GP practice in England. • If patients believe they have missing or incorrect COVID-19 vaccination data, they should be directed to call 119 and ask the call agent to make a referral to the VDRS team on their behalf. The VDRS team will then call the patient back within 5 working days. Note: VDRS will not provide clinical advice and cannot assist with queries related to vaccinations received overseas.

	Question/Topic	Things to consider
13.	Individuals registered with a Welsh GP booked for vaccination at a Mass Vaccination Centre in England	• Individuals who live in England or Wales and are registered with a GP in Wales, can receive a COVID-19 vaccine at a vaccination site in England, but must meet the Joint Committee on Vaccination and Immunisation criteria. This includes health and social care workers who work in England and are registered with a GP in Wales. • As with individuals registered with a GP in England, these patients will require their vaccination event to be entered into the point of care system (NIMS, NIVS or Pinnacle, depending on the setting). • This vaccination event data does not yet flow back to the individual's GP record in Wales, but the COVID-19 vaccine deployment programme is working with NHS Wales Informatics Service to enable that. • No further action is required by any vaccinators beyond capturing the vaccination event.
14.	Individual requesting medical exemption for COVID-19 vaccination	The Department of Health and Social Care has updated the guidance on COVID-19 medical exemptions. **From 12th May 2022 the domestic NHS COVID Pass is no longer available**: • **The medical exemptions service will no longer accept new applications from people who want to use the domestic NHS COVID Pass to prove they cannot be vaccinated for medical reasons.** • **Healthcare professionals will have until 11th July to process any applications received by 12th May.** • Individuals who applied by 12th May will automatically get the results of the application by post 2 to 3 weeks after applying. There is no need for the individual to contact the clinician reviewing the exemption unless otherwise requested by the clinician. • NHS Digital provide further process details for healthcare professionals, and have updated the Summary Care Record application to record and display information regarding a patient's COVID-19 exemption status.