Section	Page	Update/Amendment Information in V3.1 SOP COVID-19 local vaccination services deployment in community settings
2.4	10	**Preparation for Local vaccination Services** First aid and resuscitation preparation - • Links added for access to the anaphylaxis algorithm chart • resuscitation of adult COVID-19 patients primary care setting infographic • RCGP has published resources on resuscitation and anaphylaxis which can be used for CPD purposes. Anaphylaxis and Pfizer/BioNTech vaccine • Additional update relating to contraindication and precautions for Pfizer/BioNTech vaccine is available in this MHRA statement and section 4.1
3	13	**COVID-19 vaccines and the Supply Inventory List** For vaccine, consumables, PPE and SIL supply, ordering & delivery support • contact CS@nhsvaccinesupport.com or 0800 678 1650 - 7am-7pm Mon- Sun.
3.1	13	**COVID-19 vaccines** Each vaccine will be deployed with accompanying information for that specific vaccine - Available on the Specialist Pharmacy Service website.
3.1	13	**COVID-19 vaccines** Regulatory approval information specific to the Oxford/AstraZeneca vaccine
3.1	14	**COVID-19 vaccines** **Oxford/AstraZeneca vaccine** • Supplied in packs of 10 vials. • Each vial contains 8 or 10 doses of the vaccine. • The unopened multi dose vial can be stored in the fridge (stored at 2- 8OC) with a shelf life of 6 months. • The vials should not be allowed to freeze and be protected from light. Once opened the vaccine should be used as soon as possible and within 6 hours. • The vaccine may be stored between 2°C and 25°C during in use period. • Each vaccine dose of 0.5ml is withdrawn into a syringe to be administered intramuscularly. • It is normal for liquid to remain in the vial after withdrawing the final dose. • The vaccine does not contain any preservatives. • Distribution as a part of deployment can be controlled at 2-8°C. • Further packing down (splitting of packs) of lots to aid deployment can occur at 2-8°C within its shelf life and at 'room temperature' <25°C within 2 hours.
4	16	**Operating Model** **Identifying eligible patient cohorts** The Joint Committee on Vaccination and Immunisation has updated advice on prioritisation of patient groups
4	16	**Operating Model** **Patients who are ineligible for COVID-19 vaccination** For certain patient groups who should be excluded from vaccinations. • Oxford/AstraZeneca vaccine: Information for healthcare professionals and the public
4	17	**Operating Model** **Pregnancy and breast-feeding – updated guidance** • JCVI does not advise that there is a requirement for routine pregnancy testing. • Women who are trying to become pregnant do not need to avoid pregnancy after vaccination. • JCVI advises that, for women who are offered vaccination with the Pfizer/BioNTech

		or Oxford/AstraZeneca COVID-19 vaccines, vaccination in pregnancy should be considered where the risk of exposure to Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV2) infection is high and cannot be avoided, or where the woman has underlying conditions that put them at very high risk of serious complications of COVID-19. In these circumstances, clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnant women. • JCVI has advised that there is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with the Pfizer/BioNTech or Oxford/AstraZeneca COVID-19 vaccines.
4	17-18	**Operating Model** **Medical history: contraindications and precautions** A very small number of individuals have experienced anaphylaxis when vaccinated with the Pfizer BioNTech COVID-19 vaccine. • MHRA has advised that individuals with a history of anaphylaxis to food, an identified drug or vaccine, or an insect sting can receive any COVID-19 vaccine, as long as they are not known to be allergic to any component (excipient) of the vaccine. • All recipients of the Covid-19 vaccine should kept for observation and monitored for a minimum of 15 minutes. • The British Society for Allergy and Clinical Immunology (BSACI) has advised that: o individuals with a history of immediate onset-anaphylaxis to multiple classes of drugs or an unexplained anaphylaxis should not be vaccinated with the Pfizer BioNTech vaccine. The AstraZeneca vaccine can be used as an alternative (if not otherwise contraindicated) o individuals with a localised urticarial (itchy) skin reaction (without systemic symptoms) to the first dose of a COVID-19 vaccine should receive the second dose of vaccine with prolonged observation (30 minutes) in a setting with full resuscitation facilities (e.g. a hospital) o 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 • Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.
4	18	**Operating Model** **Other vaccinations** • For all patient groups, COVID-19 vaccines should not routinely be given if any other vaccination (e.g. influenza) has been received within the last 7 days. Further details are provided in the Green Book Chapter on COVID-19 vaccination page 12.
4.2	19	**Operating Model** **4.2 Dosage schedule** • For both Pfizer/BioNTech and Oxford/AstraZeneca vaccines, a two-dose schedule is advised. • The second dose of the Pfizer/BioNTech vaccine may be given between 3 to 12 weeks following the first dose. • The second dose of the Oxford/AstraZeneca vaccine may be given between 4 to 12 weeks following the first dose. Following a review of clinical evidence and latest public health data, the JCVI and the Department for Health and Social Care has published updated guidance for the NHS on the

		prioritisation of first doses of COVID-19 Vaccines. The revised guidance recommends that as many people on JCVI priority list possible should sequentially be offered a first vaccine dose as the initial priority. This will protect the greatest number of at risk people overall in the shortest possible time and will have the greatest impact in reducing mortality, severe disease and hospitalisation. Operationally this will mean that the second dose of both vaccines will be administered towards the end of the recommended vaccine dosing schedule of 12 weeks with most booked in the last week of the 12 week period.
4.3	20	**Operating Model** **Bookings** Patients registered with practices which have chosen not to sign up to the Enhanced Service… • National call and recall communications will also direct these patients how to access the National Booking System so they can secure a vaccination through another provider.
4.5	21	**Operating Model** **Consent** • The giving and obtaining of consent is viewed as a process, not a one-off event. • Consent should still be sought on the occasion of each immunisation visit. • Consent must be given voluntarily and freely • Consent remains valid unless the individual who gave it withdraws it. If there is new information between the time consent was given and when the immunisation is offered, it may be necessary to inform the patient and for them to re-confirm their consent.
	22	**Consent** **Patients who may lack relevant mental capacity** • Where the person giving consent is not the patient (e.g. is their deputy or attorney etc) the name of that person and their relationship to the patient should also be recorded.
4.8	24	**Operating Model** **Post Vaccination Observation** • For the Pfizer/BioNtech COVID vaccine, recipients should be monitored for 15 minutes after vaccination, with a longer observation period when indicated after clinical assessment, as set out in the MHRA statement. • For the Oxford/AstraZeneca there is not a requirement for 15 minutes observation unless this is indicated after clinical assessment
5	26	**Appendix A Workforce Planning** • Workforce support offer available to all COVID-19 vaccination centres. • Each Integrated Care System (ICS) has a designated Workforce Lead Employer which will act as an operational workforce hub for the all vaccination providers in the local area. • They can provide both health care professionals for employment such as returners to professional lists and volunteers such as St John's Ambulance staff. • The Lead Employer will work with all providers on workforce communications, management of rostering systems for volunteers and National Workforce suppliers and will have oversight of mandatory and statutory training of these staff.
5	30	**Appendix D:** **Guidance for COVID-19 vaccination in care homes that have cases and outbreaks** • COVID vaccine should be offered to older adults in care homes and their carers • This includes when other residents have been diagnosed as having COVID-19 infection. • A number of factors will need to be considered before an immunisation team attends a care home. It is recommended that a risk assessment is carried out by the lead

		vaccinator and that this is performed in conjunction with the care home manager. • If needed, advice should be sought from others such as the local health protection team, CCG infection prevention and control lead and local Director of Public Health. Further guidance
5	36	**Appendix D - Vaccine provision for care homes** In addition to the Pfizer vaccine PCNs may access Oxford/AstraZeneca vaccine for use in small care homes and housebound patients.
	39	**Appendix D - Vaccine provision for care homes** **Cold Chain Management** • PCNs should follow the relevant vaccine SPS SOPs. • The lead GP must be familiar with the relevant legislation (see Chief Pharmaceutical Officer's letter) and be sure at all those involved in storing, handling, preparing and administering the vaccine are competent to do so.
	41	**Appendix D - Vaccine provision for care homes** **Vaccine cold chain properties** Oxford/AstraZeneca • Distribution as a part of deployment can be controlled at 2-8°C throughout its shelf life of 6 months. • The vaccine must not be allowed to freeze and be protected from light. • Further packing down (splitting of packs) of lots to aid deployment can occur at 2-8°C within its shelf life and at 'room temperature' <25°C within 2 hours. • Once a vial is opened use as soon as practically possible and within 6 hours. The vaccine maybe stored between 2°C and 25°C during the in-use period.
5	44	**Appendix E Newly added appendix– Housebound Residents** **(Copied in entirety)** There are some patients living in the community who usually receive treatments at home and are generally classed as housebound. For this group consideration needs to be given to the best approach for vaccination. • General practice teams to determine approach, alongside the community teams, for patient that are housebound based on their knowledge of the patient and circumstances. Some of these patients may be able to attend PCN designated sites with assistance and discussion should be held with the family and /or carer to facilitate this process. • There will be a cohort of patient who are completely housebound and unable to travel to PCN designated site for immunisation even with assistance. For these patients the Oxford/AstraZeneca vaccine may be most suitable for use. • The pre vaccination procedure including checking patient for eligibility, contraindications precautions, booking date/time, consent and best interest decision who lack capacity follows the same principles as detailed in Section 4. • Due consideration should be given to those who live alone and those who lack mental capacity as this situation may require further preparation. **Workforce considerations** The PCN should consider the best model to deliver vaccination to housebound given a collaborative approach with the community teams and available skill mix. We recommend that the visiting team includes 2 people (1 lead vaccinator and 1 person to support). **On the day of the vaccination** appointment practices should call ahead to check that the person is well and to remind them of their appointment, check there will be someone to let the HCP in and if there is someone else at home with the person ask if it would be possible to open windows to provide ventilation shortly before the arrival time. **Supply inventory list**

		Before setting out for the appointment, HCPs should ensure they have all the equipment in the Supply Inventory List. **Arrival at the address** HCP should put on appropriate PPE before entering the person's home. If windows not already open, ask carer/family member if possible, to do this. As far as possible try to maintain a two-metre distance from people other than the person being vaccinated. **Clinical review of the patient and obtaining written consent (if feasible)** Before administering the vaccination, a clinical review can be undertaken to determine if the patient is fit to receive vaccination. If needed, written consent could also be provided at this time. **Delivery of vaccination** • Preparation and administration of Oxford/AstraZeneca vaccine as per guidance in SPS. • A record of the vaccination should be made in the patient's medical records and on Pinnacle. **Post vaccination observation** • The HCP should remain with the person for 15 minutes after the vaccination has been given and monitor them for any signs of an adverse reaction. • Patients should be given a post vaccination record card with details of their vaccination and informed that they will be contacted about the second dose. • They or their carer should also be given a leaflet about possible side effects and this could be explained to them/their carer during part of the 15 minutes. • Patients and/or their carers should know who to contact if they are concerned about any effects that maybe experienced after the vaccination. In most cases, this is the patient's own GP. • On leaving the patient's home, PPE should be removed and disposed of in line with Section 3.3 (waste Management) in this SOP.