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Novel coronavirus (COVID-19) standard operating procedure

COVID-19 local vaccination services deployment in community settings

This guidance is correct at the time of publishing. However, as it is subject to updates, please use the hyperlinks to confirm the information you are disseminating to colleagues and the public is accurate.

Any changes since v3.3 (8 March 2021) are highlighted in yellow.

The document is intended to be used as a PDF and not printed: weblinks are hyperlinked and full addresses not given.

The latest version of this guidance is available here.

To provide feedback about this SOP please complete this email template.

Contents

1. Scope

This standard operating procedure (SOP) applies to all providers who have been contracted to provide local vaccination services in community settings including at NHS sites (GP Practices, Community Pharmacies), non-NHS sites, care homes, temporary vaccination clinics used to improve uptake in specific groups (see Appendix H), and patients' own homes. All NHS and non-NHS sites providing vaccination will have been 'designated' via a Commissioner-led site assessment process.

Some aspects of this document may only be appropriate to certain types of site and/or provider, and where clear that is indicated. However, we trust healthcare professionals to use their clinical judgement when applying this guidance in what we appreciate is a highly challenging, rapidly changing environment.

1.1 General guidance and advice

Providers should continue to apply measures and best practices adopted during the pandemic for providing primary care services in the context of COVID-19, as set out in the general COVID-19 SOPs for general practice / community pharmacy, and continue to take reasonable steps to keep our staff and patients safe.

This SOP describes the operating model and design requirements for safe delivery of COVID-19 vaccines in the community and must be read in conjunction with:

- Enhanced Service Specification: COVID-19 vaccination programme for general practice (GP-led vaccinations only)
- Local Enhanced Service Agreement: COVID-19 vaccination programme for community pharmacy (community pharmacy-led vaccinations only)
- COVID-19: vaccination programme guidance for healthcare practitioners
- The Green Book, particularly chapter 14a: COVID-19 - SARS-Cov-2
- Public Health England COVID-19 vaccination programme webpage which includes guidance, training resources, and other relevant materials.

NHS England's guidance and letters about the COVID-19 vaccination programme are on our website, and other resources are on the FutureNHS workspace. New

users can register to join the platform by emailing P_C_N-manager@future.nhs.uk from an NHS email address (or similar work email address of eligible users).

2. Preparation for local vaccination services

Prior to commencing vaccination, commissioners and providers will work together to mobilise community sites to get ready for delivering vaccinations. Further information on the mobilisation process for designated sites is sent by NHS England and NHS Improvement in advanced of the site's mobilisation. This section should be read in conjunction with those communications.

2.1 Leadership and Governance

Clinical and operational leadership

All providers must appoint a clinical lead and operational lead who will be responsible for the delivery of all aspects of local vaccination services in all settings relevant to that provider. This leadership should lead the development and implementation of local delivery plans to ensure all systems and processes, workforce (with clearly defined roles and responsibilities), training and all other relevant preparatory requirements are in place to support delivery of local vaccination services. The clinical lead is also the lead for infection prevention and control, unless this is designated to another individual.

PCN-led sites should determine the most appropriate clinical supervision required, based on local circumstances. It is expected that the majority of vaccinations will be delivered by healthcare professionals under a Patient Group Direction (PGD) or by lay vaccinators under the COVID-19 National Protocol. If other healthcare professionals have the relevant skills and are working under a PGD, the presence of GPs is not an essential legal requirement. However, many have found that the presence of a GP is helpful in a "Clinical Director" type capacity to assist with consent and complex patients. GP practices remain responsible for the conditions set out in the Enhanced Service.

There is a requirement for Community Pharmacy sites to be overseen by a pharmacist.

All providers should ensure they are engaged with their local commissioners and systems to support cross-system planning (e.g. workforce) and regular information reporting (e.g. regular sitreps) as required to support insight and development of the operating model. Commissioners should offer all possible assistance to providers to mobilise sites and prepare for vaccination administration.

All providers must also ensure all staff involved in local vaccination services are aware of escalation processes for clinical incidents and enquiries, which can be found on our website. This should include reporting any suspected vaccine side effects or adverse incidents related to the use of the vaccines to the MHRA via the Coronavirus Yellow Card reporting site.

Safe and secure handling and management of COVID-19 vaccines

COVID-19 vaccines have very specific handling requirements which are a condition of temporary authorisation (Pfizer/BioNTech and Oxford/AstraZeneca) under Regulation 174 of the Human Medicines Regulations 2012.

The characteristics of the different vaccines vary considerably. The product characteristics are available in the relevant 'Healthcare Professional Factsheet' and patient information in the 'Consumer Factsheet'.

Some vaccines are inherently unstable at higher temperatures or when agitated so maintaining the correct cold chain or preparation technique is critical to maintain the integrity and therefore effectiveness of all vaccines.

Vaccines that have not been transported or stored correctly may be ineffective or harmful; they would therefore no longer be within the conditions of their temporary authorisation and must not be used. The Lead Responsible CCG Chief Pharmacist will support staff by ensuring safe and secure handling and use of vaccines at PCN designated sites, with the Responsible Pharmacist at a Community Pharmacy site assuming that role. Vaccines must be transported only in approved and validated cool boxes, and the temperature of the cool box and contents must be monitored and reviewed before use in order to maintain cold chain requirements. Means of detecting when a temperature excursion has occurred are required and that any 'out of specification' recordings are addressed promptly and appropriately, and that a full audit trail is maintained. Please see section 3.1 for information on movement of the vaccine.

The focus on avoidance of waste should also be of high priority. In addition to complying with COVID-19 vaccine specific guidance, providers should ensure that processes for the safe and secure handling and storage of vaccines are in place in accordance with principles and guidance encompassed in the Chief Pharmaceutical Officer's letter of 8 December and 31 December 2020, which sets out the governance, handling, and preparation of vaccines by Local Vaccination Services. Specific guidance regarding safe and secure handling of the specific vaccine can be found on the Specialist Pharmacy Services website. Regulatory compliance by the doctor/GP under Regulation 3 of the Human Medicines Regulations 2012 means they have to understand the process being performed in their name and be accountable for it.

The provider must ensure that appropriate and formal authorisation for vaccine supply, preparation and administration is in place. Patient Specific Direction (PSD) for Oxford/AstraZeneca, Patient Group Direction (PGD) for Pfizer/BioNTech and Oxford/AstraZeneca, or the National Protocol for Pfizer/BioNTech and Oxford/AstraZeneca can be used for these purposes, although the details and requirements of each differ. A summary of the different legal mechanisms of administration are here. Additional PGDs, PSDs and National Protocol documents will be published in relation to each vaccine that becomes available. The staff groups who supply, prepare and administer the COVID-19 vaccine must be those defined as eligible to do so. They must have signed the relevant PGD or National Protocol that they are working under, and must be competent to perform the tasks they are asked to carry out.

This means systems and processes must be in place to maintain product integrity, medicines governance, and risk management of COVID-19 vaccines, recognising the significant additional considerations and conditions that may apply compared to other vaccination programmes. It is therefore critical that the products are handled correctly in accordance with the detailed SOPs on the Specialist Pharmacy Service's website. Providers should initially contact the Lead Responsible CCG Chief Pharmacist, who will then contact the relevant Specialist Pharmacy Services Regional Quality Assurance Specialist or Regional Chief Pharmacist for additional guidance and support.

Vaccine security and crime prevention

Providers and all staff on site (including contractors and volunteers) should be alerted to the risk associated with vaccines, vials, remnants, packaging, and consumables (eg, needles) and waste (as per section 3.3 of this SOP) being obtained by criminals, that could present a danger to the public and impair the integrity of the vaccine programme.

Therefore, providers must take steps to ensure vaccines, vials, remnants, packaging, consumables (eg needles) and waste (see section 3.3) are securely controlled at all times, to prevent both unauthorised access and opportunities for theft, criminal reuse or falsification for exploitation, eg, stolen vials being re-filled and sold, or reused packaging making counterfeit vaccines appear legitimate on the black market. Every member of staff and volunteer at a vaccination site has a vital role to play in ensuring vaccine security and mitigating the associated risks.

2.2 Workforce

Providers should consider short-term capacity implications associated with releasing staff to undertake COVID-19 vaccination specific training and the period of time over which staff will need to be trained. PHE has developed training resources and eLearning for staff, which can be found on the GOV.UK website.

Providers are responsible for ensuring that any staff involved in vaccinations are appropriately trained and the appropriate documentation is in place for indemnity purposes, such as a volunteer agreement for engaging volunteers or a staff sharing memorandum of understanding between providers. Further information regarding the indemnity arrangements that apply for PCN COVID-19 vaccination services can be accessed on NHS Resolution's website. Community Pharmacy sites have been provided with a letter confirming indemnity provision.

Providers should consider the medium-term capacity implications of releasing staff to deliver the vaccination programme. Vaccine supply will vary from week to week and sites should ensure there is flexibility in workforce plans to enable teams to quickly be stood down in quieter periods and stood back up when required. For community pharmacy-led sites, flexibility will also be necessary to respond to National Booking Service appointment uptake.

Guidance has been issued to help PCNs and Community Pharmacy access the National Workforce Supply Routes. LVS sites should consider how best to maintain workforce resilience including by drawing down on this additional support. The Lead Employer can help you access this and the following roles:

- Vaccinators, Clinical Supervisors and Registered Healthcare Professionals from NHS Professionals. These candidates will require local onboarding, training and checks before being deployed to a site.
- Volunteer vaccinators, patient advocates and post-vaccination observers supplied by St John Ambulance. These are provided free of charge.
- Volunteer stewards supplied by NHS Volunteer Responders, led by Royal Voluntary Service. These are provided free of charge.
- Clinical and GP Returners who have offered support to the NHS by taking part in the COVID-19 vaccination programme.

A Statutory Instrument was agreed to amend the Human Medicines Regulations, enabling the expansion of workforce and the breaking down of vaccination activity into component parts. The legislative changes allow unregistered staff with appropriate training to administer the vaccine under the National Protocol, thereby reducing the need for the clinical team to be composed solely of registered healthcare professionals.

The national workforce supply routes have capacity to support Providers with over 10,000 unregistered vaccinators. In addition, St John Ambulance is providing volunteers who can support (with the relevant pre-requisite training and competency sign off) as unregistered vaccinators. Providers should consider the optimum skills and staffing mix, including the use of unregistered vaccinators, to ensure a sustainable and efficient workforce delivery model.

Finally, to further support workforce resilience, both individual and team-level coaching is available to all staff through the LookingAfterYouToo and LookingAfterYourTeam programme. These free-of-charge sessions can be booked here.

Further advice on workforce planning is in Appendix A.

2.3 Site preparation

All providers administering vaccinations will have been designated in line with the relevant Site Designation Process which includes site requirements (available online for GP practice and community pharmacy led-sites).

Access

Providers should ensure that their local vaccination services are accessible to all members of their community and take reasonable steps to improve access and reduce potential inequalities for people eligible to access vaccinations.

This includes having access to translation and interpretation services as required to support consent, mental capacity and clinical assessments. It may be helpful to have supporting literature available in a range of languages and easy read formats

appropriate to the population being served (see the section on ‘Communicating for diversity and inclusion’ in 4.3 below). Contact your commissioner for information about local translation and interpretation services.

Patients, including NHS staff, do not require an NHS number or GP registration to receive a vaccination and should never be denied one on this basis, either in person when presenting for a vaccine, or through booking systems.

General-practice providers should note that for COVID-19 vaccination, the Enhanced Service permits the vaccination of unregistered patients to ensure these patients are able to access local vaccination services, and to ensure their unregistered status is not a barrier to them accessing local vaccination services. Patients should be encouraged to register with a general practice. A range of resources are on the FutureNHS workspace to help encourage people to register with their GP.

Community pharmacy providers should seek ways to encourage uptake of vaccine, particularly in populations where uptake is low. Local booking is permissible under the terms of the LES in agreement with the NHS England regional team.

PCN and Community Pharmacy sites should work collaboratively to target underserved populations in the most effective way possible using all providers.

More information about other potential health inequalities and inclusion groups can be found in Appendix B.

COVID-secure, social distancing and patient flow

Please refer to the Health and Safety Executive guidance on making your workplace COVID-secure, government guidance on working safely during coronavirus (COVID-19), guidance on social distancing and guidance on wearing of face coverings.

The following advice may also be helpful where vaccinating on-site:

- Use clear signage to direct patients to the appropriate site/space on arrival.
- Ensure alcohol gel/handwashing facilities are readily available for patients and staff, including at site entrances.

- Where possible, configure sites to support linear patient flows and have separate or clearly partitioned entrances and exits. This will be particularly helpful for enabling higher flow rates. Where necessary, offer queuing support to maintain social distancing.
- De-clutter communal spaces and clinical rooms to assist decontamination.
- Communal areas should allow for physical distancing between patients; consider the use of floor markings, seating arrangements, signage and queue marshalling to support this. This should apply for patients at all stages of the operating model.
- Provide adequate ventilation by opening windows – even partially will help to keep a flow of air through an area.
- Ensure rooms or suitably private spaces are available to complete consent/capability and clinical assessments and vaccine delivery to enable patient confidentiality and privacy.
- Ensure there is sufficient fridge capacity for vaccines, that the area is secure and there is an area suitable for vaccine preparation.
- Ensure there is sufficient secure storage space for the vaccine consumables and waste generated by the local vaccination service.
- Consider measures such as asking patients to wait in private vehicles or designated external waiting areas, where possible, to reduce numbers in communal spaces during busy periods.
- Staff should wear the appropriate PPE and pay attention to social distancing with each other. Lateral Flow Tests (LFTs) should also be used for regular testing of staff at LVS sites.

Guidance on infection prevention and control (IPC) within health and care settings advises that "Physical distancing of 2 metres is considered standard practice in all health and care settings, unless providing clinical or personal care and wearing appropriate PPE.'' If it is not practicably possible to maintain social distancing this must be raised urgently through your Regional Vaccination Operations Centre (RVOC).

Social distancing tips from sites:

- Place well informed marshals and volunteers at entry points, reminding the public of the need to social distance.
- Daily updates with staff reiterating the IPC guidance in detail.
- Place volunteers throughout the exit process to make sure there isn't crowding in corridors and lifts as people leave.
- Use HSE COVID-secure guidance and mark out maximum occupancy in areas with clear signage for the public.

- Close oversight of flow and compliance.
- People often arrive early for vaccination appointments, and plans around queuing and waiting areas should take this into account.

Providers vaccinating in care home settings and patients' own homes should put in place procedures appropriate to those settings, including considering how to limit the number of different workforce attending these sites to minimise any risk of transmission of COVID-19.

Site security

PCN Providers must follow any usual requirements set by the Care Quality Commission (CQC). Community Pharmacy Providers must follow any usual requirements set by the General Pharmaceutical Council (GPhC). Any LVS Provider must have regard to any other relevant professional regulators involved in the provision and staffing of their site for securing all aspects of the designated sites, and any conditions of Marketing Authorisation for the vaccine.

Providers should liaise with their commissioners, local resilience forums and the police to put in place any reasonable security requirements for the local vaccination services and to ensure the police are aware of the location. Providers should consider site security (including staff, locks and alarms) if storing vaccine and/or clinical waste overnight, particularly in non-NHS sites. Providers should report any incidents to the police, as well as raising any issues or incidents with their commissioner and Regional Vaccination Operations Centre (RVOC). More information is in the Standard operating procedure for the management of COVID-19 vaccination clinical incidents and enquiries.

IT equipment and systems

Prior to starting vaccination, providers should have tested I.T. equipment and ensured relevant staff have received training and can access from the site the different clinical and non-clinical systems relevant to COVID-19 vaccination. These include:

- Q-flow National Booking System (not applicable to GP practice providers who will utilise local collaborative booking systems for designated sites). Log-ins to this system and support with making appointments live for booking should be done several days in advance of the first vaccine supply date to support a good level of bookings at site activation.

- Outcomes4Health/Pinnacle Point of Care System for recording the vaccination event.
- NHS Business Services Authority Manage Your Service tool to support the payment of the Item of Service COVID-19 vaccination fee to providers.
- Foundry reporting system or any other systems as directed by the commissioner.

Providers will be given access to the relevant systems and associated training as part of the site onboarding process. All sites, particularly those who will be delivering clinics from new, non-NHS sites, should ensure that they have appropriate broadband connectivity. Non-NHS sites will be supplied with a 4G/router as standard.

Training material on the main systems is on the FutureNHS workspace.

Any issues can be raised via the IT services helpdesk: vaccineservicedesk@england.nhs.uk / 0300 200 1000 open 6am-10pm every day, including Bank Holidays.

2.4 First aid and resuscitation preparation

Providers should reasonably anticipate three medical emergencies associated with vaccination: fainting, hyperventilation, and anaphylaxis.

All designated sites should at a minimum include a registered healthcare professional trained within the previous 18 months in the management of anaphylaxis, cardiopulmonary resuscitation, and use of an automated external defibrillator. PHE has included resuscitation training within the COVID-19 vaccination programme training resources, which can be found on the GOV.uk website.

All designated sites will be provided with resuscitation equipment and medications via the Supply Inventory List; see section 3.2. Some sites may wish to have additional equipment or medicine as recommended by The Resuscitation Council UK, due to local circumstances, and can complete a local resuscitation risk assessment to consider as a minimum the following:

- Location (Remoteness)

- workforce (including the consistent presence of healthcare professionals with advanced skills in resuscitation)
- Volumes of patients presenting (quantities of equipment and workforce requirements)
- Quantities of equipment / medicines held

Access to an Automated External Defibrillator is not required for roving vaccinators. Access to this guidance on management of anaphylaxis in the vaccination setting, anaphylaxis algorithm chart and the resuscitation of adult COVID-19 patients primary care setting infographic may be helpful. In addition, the Royal College of General Practitioners (RCGP) has published resources for all primary healthcare professionals on resuscitation and anaphylaxis which can be used for CPD purposes.

Access to oxygen for roving vaccinators should be determined by individual risk assessments, taking into account the number of patients that will be vaccinated during the roving visit.

Anaphylaxis and Pfizer/BioNTech vaccine

An MHRA protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever the Pfizer/BioNTech vaccine is given. 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. Vaccine recipients should be monitored for 15 minutes after vaccination, with a longer observation period when indicated after clinical assessment. More information is available in this MHRA statement.

Additional requirements may also be needed when future vaccines are available. These will be notified to providers by service commissioners.

For the Oxford/AstraZeneca vaccine there is no requirement for 15 minutes observation unless this is indicated after clinical assessment or where the patient has experienced an adverse reaction to a previous vaccination dose.

2.5 Occupational health requirements

Providers should ensure they have a local needlestick injury protocol accessible (ideally displayed) on site which should include contact details for any relevant occupational health service and that staff understand what to do should they experience a needle stick injury. The provider is responsible for ensuring a nominated individual on site has knowledge and understanding of local needlestick protocols and ensure that they are followed.

2.6 Infection prevention and control (IPC)

Infection control precautions are to be maintained by all staff, in all settings, at all times, for all patients; please refer to the latest IPC guidance. This includes videos and posters demonstrating correct procedures for donning and doffing personal protective equipment (PPE).

The IPC guidance states that for administration of vaccines, healthcare workers must perform hand hygiene between patients and wear a sessional fluid-resistant surgical facemask (FRSM).

A patient and procedure risk assessment for vaccine administration may be completed (as recommended by the IPC guidance) to consider the likely risk of exposure to blood, body fluids and respiratory droplets, which in turn will inform the need for any additional PPE. This should take into account factors such as the prevalence of COVID-19 infection in their locality, the health status of the person being vaccinated, the route of administration, model of delivery and any relevant environmental factors. If further advice is needed, contact your local infection prevention and control team.

3. COVID-19 vaccines and the Supply Inventory List

For vaccine, consumables, PPE and SIL supply, ordering & delivery support, please contact CS@nhsvaccinesupport.com or 0800 678 1650 - 7am-7pm Mon- Sun.

3.1 COVID-19 vaccines

Each vaccine will be deployed with accompanying information for that specific vaccine and will include advice for health professionals about the vaccines, on ordering, stock management, transporting stock, preparation of dose, disposal and dealing with spillages. These documents are available on the Specialist Pharmacy Service website.

Regulatory approval information specific to the Pfizer/BioNTech vaccine can be found here.

Regulatory approval information specific to the Oxford/AstraZeneca vaccine can be found here.

Further approvals information will be made available as and when other vaccines become available.

Guidance on safe practice for handling multiple COVID-19 vaccines is published by the Specialist Pharmacy Service: https://www.sps.nhs.uk/home/covid-19-vaccines/

Pfizer/BioNTech vaccine

Vaccine should be prepared in accordance with manufacturer's recommendations (see Regulation 174 Information for UK Healthcare Professionals) and NHS standard operating procedures for the service.

Each vial contains at least 5 doses. It is normal for a small amount of liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial after 5 doses have been extracted may be sufficient for an additional (sixth) dose. Care should be taken to ensure a full 0.3ml will be administered. Where a full 0.3ml dose cannot be extracted the contents should be discarded. Any unused vaccine should be discarded 6 hours after dilution.

The manufacturer's product information leaflet is here.

Pfizer has published education materials which include a video and poster for handling, preparation and administration of the vaccine, and a background and evidence slide set for healthcare professionals: www.cvdvaccine.co.uk.

Oxford/AstraZeneca vaccine

Vaccine should be prepared in accordance with the manufacturer's recommendations (see Regulation 174 Information for UK Healthcare Professionals) and NHS standard operating procedures for the service.

The COVID-19 Vaccine AstraZeneca (ChAdOx1-S [recombinant]) comes in both 10-dose vials of 5ml and 8-dose vials of 4ml. Each vial contains at least the number of doses stated. It is normal for liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for an additional dose. Care should be taken to ensure a full 0.5ml dose is administered. Where a full 0.5ml dose cannot be extracted, the remaining volume should be discarded.

The manufacturer's product information leaflet is here.

Any unopened multi dose vial can be stored in the fridge (stored at 2-8^{O}C) with a shelf life of 6 months (as marked on the vaccine box). Vials should not be allowed to freeze and should be protected from light. Once opened the vaccine should be used as soon as possible and within 6 hours. The vaccine should be stored between 2^{O}C and 25 ^{O}C during in use period.

Distribution as a part of deployment should be controlled at 2-8^{O}C.

Further packing down (splitting of packs) of lots to aid deployment can occur at 2-8^{O}C within its shelf life and at 'room temperature' <25^{O}C within 2 hours.

Movement of vaccine

We wrote to sites on 7 January to provide advice on the movement of the Oxford/AstraZeneca vaccine between practices within a PCN grouping, or outside the PCN grouping where specific sub-contracting arrangements are in place. A subsequent position statement on the use of the Oxford/AstraZeneca vaccine to visit housebound patients provides guidance on safe transport and use of punctured vials. There is also equivalent guidance for the use of the Oxford/AstraZeneca vaccine in and between care homes. LVS sites should follow

both sets of guidance to ensure safe transfer of vials between all residential settings and aseptic technique.

The policy on the transfer of COVID-19 vaccines between Hospital Hubs, Vaccination Centres and Local Vaccination Services ('mutual aid') can be found here. In general, there should be no mutual aid between any organisations as they are expected to use the supplies made available and delivered directly to them to vaccinate their patients. Annex B of the policy contains further information on the movement of any vaccine between a PCN grouping and/or a third party, which is a general exception to the policy.

Community Pharmacy providers wishing to move vaccine between designated sites must have the advance permission of their Commissioner (and the Commissioner of the receiving site if that is different).

Staff training for local vaccination services

All staff involved in the delivery of COVID-19 vaccination will need to undergo training, the extent of which will vary depending on the staff member's role and experience. All vaccinators will need to undertake training on the specific vaccine being administered.

PHE has published COVID-19: vaccinator training recommendations, Immunisation training standards for healthcare practitioners, and COVID-19 specific vaccine e-learning.

Further product-specific training will be made available as additional COVID-19 vaccines become available.

3.2 Supply Inventory List (SIL)

The Supply Inventory List (SIL) is a 'free of charge' generic equipment and consumables list, which provides what is needed to effectively administer vaccinations. The volume of consumables has been proportioned to the number of vaccines and will be replenished automatically with each vaccine order; designated sites are not required to order items on the SIL. Any issues with over or under-supply should be raised via the helpdesk CS@nhsvaccinesupport.com or 0800 678 1650 - 7am to 7pm, seven days a week.

More information about the SIL and what equipment and consumables will be provided for different types of sites can be found on our website. Full information will be provided to sites as part of the site mobilisation and onboarding process.

If sites require additional items not on the centrally supplied lists, they should discuss this with their commissioner who may be able to provide the items or reimburse reasonable costs, where these have been agreed in advance, associated with site set-up from centrally provided funding the costs of the provider purchasing the items. Further guidance is available on FutureNHS.

3.3 Waste management

It is vital that vaccination sites segregate all waste into the proper waste stream. Doing so reduces pressure on the waste services infrastructure, reduces the impact on the environment, significantly reduces costs, and ensures compliance with relevant waste regulations.

All waste should be disposed of into the allocated consumables and stored securely on site, or transferred to another site as required (eg roving vaccinators) following each vaccination session.

The principles of the COVID-19 waste management SOP should be followed, with the following advice specific to the COVID-19 vaccination programme:

Tiger striped (offensive) waste bag 	**PPE** (eg facemasks) and **swabs** (including contaminated with blood) should be disposed of as offensive waste and placed into the **tiger striped bags**. Swabs should not be put into the sharps bins.
Yellow lidded (medicine contaminated sharps/vials) waste bins	All **needles**, **syringes** and **vials** should be disposed of as clinical waste and placed into the **yellow lidded sharps bins**. Vials must be put in the sharps container to prevent vaccine vials from being stolen or used to facilitate counterfeit vaccines.

	Vials and syringes should not be placed in any other packaging/wrappers/bags before being put into the sharps bin, to maximise space available for vials/syringes. Following constitution of the Pfizer vaccine vials, please depress all syringe plungers (reconstitution) to expel any content (eg, air) before disposal in the sharps bin to reduce the size of the syringe unit and maximise space available in sharps bins. If sharps bins are part-filled at the end of a vaccination session, secure these (eg, in lockable storage) until the next session when they can continue to be used; avoid leaving them insecured by vaccination stations, or closing the lid and disposing of part-filled containers, to maximise containers and reduce waste.
Confidential waste 	All **vaccine branded** packaging which includes identifiable and sensitive information about the vaccine should be defaced, destroyed, and disposed of as **confidential** waste (as per SPS SOPs). This is to ensure patient safety, as well as to prevent vaccine packaging from being stolen and criminally reused or falsified for exploitation, e.g, making counterfeit vaccines to appear legitimate on the black market.
Recycling waste 	All **non-vaccine branded** cardboard packaging should be disposed of as **recycling.** Where possible please recycle other materials too.
Black bag (domestic) waste	All non-recyclable waste such as syringe wrappers should be placed in **domestic** waste.

	
Dry Ice waste 	Any dry ice used for storage and transport of vaccines (if applicable) should be placed in a secure well-ventilated area at room temperature, and allowed to sublimate away. Dry ice must not be disposed of through other waste containers or down sinks/toilets or outside drains.

Please work with your commissioner to confirm how each of these waste types will be collected from vaccine sites.

Yellow (infectious & contaminated) waste bag 	Yellow clinical waste bags are for infectious waste contaminated with medicines/chemicals only. As vaccine waste is not infectious waste, these should not be used. Please ensure these bags are not available in vaccination sites.
Orange (infectious) waste bags 	Orange clinical waste bags are for infectious waste (not contaminated with medicines/chemicals). As vaccine waste is not infectious, these should not be used. Please ensure these bags are not available in vaccination sites.

If you are receiving these bags incorrectly in the SIL or have any other issues with getting the right type of waste container, please contact the national helpdesk to escalate the issues. They will ensure you have access to the right equipment and consumables to support good waste management: cs@nhsvaccinesupport.com or 0800 678 1650.

4. Operating model

The operating model set out below is intended to be described generically and apply to all settings in scope of this SOP; this will need adapting for the type of setting you are delivering local vaccination services in, i.e. whether patients are attending an NHS site (e.g. GP practice, hospital or community pharmacy) or a non-NHS site (e.g. community centre, fire station, museum etc). The principles of this section also apply for roving vaccinations e.g. care homes and patients own homes but should be read in conjunction with Appendix D (care homes) and Appendix E (Housebound).

Clinicians must be satisfied that patients meet the acceptance criteria for each 'check-point' of the operating model before proceeding to the next step.

A visual overview of a suggested process for a fixed site can be found in Appendix C and for care homes in Appendix D which may be helpful.

4.1 Identifying eligible patient cohorts

The Joint Committee on Vaccination and Immunisation's advice on prioritisation of eligible patient groups can be found here. Providers should follow guidance from the commissioner on phasing access to different patient groups.

PCN-led sites are responsible for using existing local patient systems to identify eligible patient cohorts based on age or risk status and inviting them for vaccinations, following the cohort prioritisation timelines advised by NHS England through the vaccine allocation process. For community pharmacy-led sites, the National Booking Service will invite people in accordance with the cohort prioritisation timelines. Community pharmacy-led sites must conduct appropriate checks to confirm the eligibility of frontline health or social care workers using, for example, a work photo ID card, authorisation letter from the local authority, a signed letter of authorisation from their employer or wage slip that is dated within the last 3 months.

Where community pharmacy-led sites undertake local booking under the terms of the LES they will also be responsible for identifying eligible patient cohorts based on age or risk status and inviting them for vaccinations in accordance with the cohort prioritisation timelines advised by NHS England through the vaccine allocation process.

Operational guidance for the vaccination of frontline health and social care workers sets out the steps to ensure maximum uptake of vaccination and timely, equitable access across staff groups. There is also a standard operating procedure (SOP) for vaccine deployment in frontline social care workers who are not already included within JCVI priority cohort 1 (those that work within CQC registered care homes for older adults). Frontline health and social care workers are also now able to book appointments with a community pharmacy-led site using the National Booking Service.

Guidance on the definition of JCVI cohort 6 can be found in Annex B of this letter and information on vaccinating adult carers can be found in this letter and in the standard operating procedure for unpaid carers. According to the JCVI and Public Health England Green Book, adult carers are "those who are eligible for a carer's allowance, or those who are the sole or primary carer of an elderly or disabled person who is at increased risk of COVID-19 mortality and therefore clinically vulnerable". Two data sources are being used to identify those who are eligible within this definition: those flagged as carers in GP systems, and those assessed by DWP as eligible for a carer's allowance. Those who have a carer's flag on GP systems are being called by PCN LVSs, as in many cases they will accompany the person they care for if they are also being vaccinated in cohort 6, for example those with learning disabilities. From Saturday 20 February those identified within these groups will be able to book via the National Booking Service.

Additional patients have been identified by COVID-19 population risk assessment. This has been used at a national level to identify additional groups of patients with specific multiple risk factors which, when combined, may put them at a similar risk to those who are clinically extremely vulnerable to severe outcomes. As a precautionary measure this group will be added to the shielded patient list (SPL) on advice of the Chief Medical Officer (CMO), to enable them to be prioritised for vaccination. Further details are available in the letter of 15 February found here.

Patients and NHS staff do not require an NHS number or GP registration to receive a vaccination and should never be denied one on this basis, either in person when presenting for a vaccine, or through the design of booking systems. If a patient has not been issued with an NHS number, then providers should vaccinate now, record locally via a paper system and ensure that the vaccination event is recorded on Outcomes4Health/Pinnacle at a later date. NHS England and NHS Improvement are looking into a longer-term solution, but providers should not wait for this before

vaccinating. Providers will be advised once a solution is in place so they can transfer the vaccination record on to Outcomes4Health/Pinnacle and be paid for these vaccinations in the next payment period.

Vaccination suitability for special patient groups

The Green Book (chapter 14a) is updated on a regular basis. Some recent clarifications have been made including about individuals on stable anticoagulation therapy; patients who are about to receive planned immunosuppressive therapy; and children with neurological comorbidities. Providers should regularly refer to the Green Book for more information. Further information on vaccination of children is in Annex A of this letter.

Patients who are ineligible for COVID-19 vaccination

The Medicines and Healthcare products Regulatory Agency (MHRA) and/or the manufacturer of COVID-19 vaccines may provide guidance for certain patient groups who should be excluded from vaccinations.

- Pfizer/BioNTech vaccine: Information for healthcare professionals and the public
- Oxford/AstraZeneca vaccine: Information for healthcare professionals and the public

All providers are responsible for checking published information about the COVID-19 vaccines, but we have included some exclusions here for emphasis.

Clinicians should apply professional curiosity to assess, as part of the pre-vaccination clinical assessment, the likeliness of these exclusions applying.

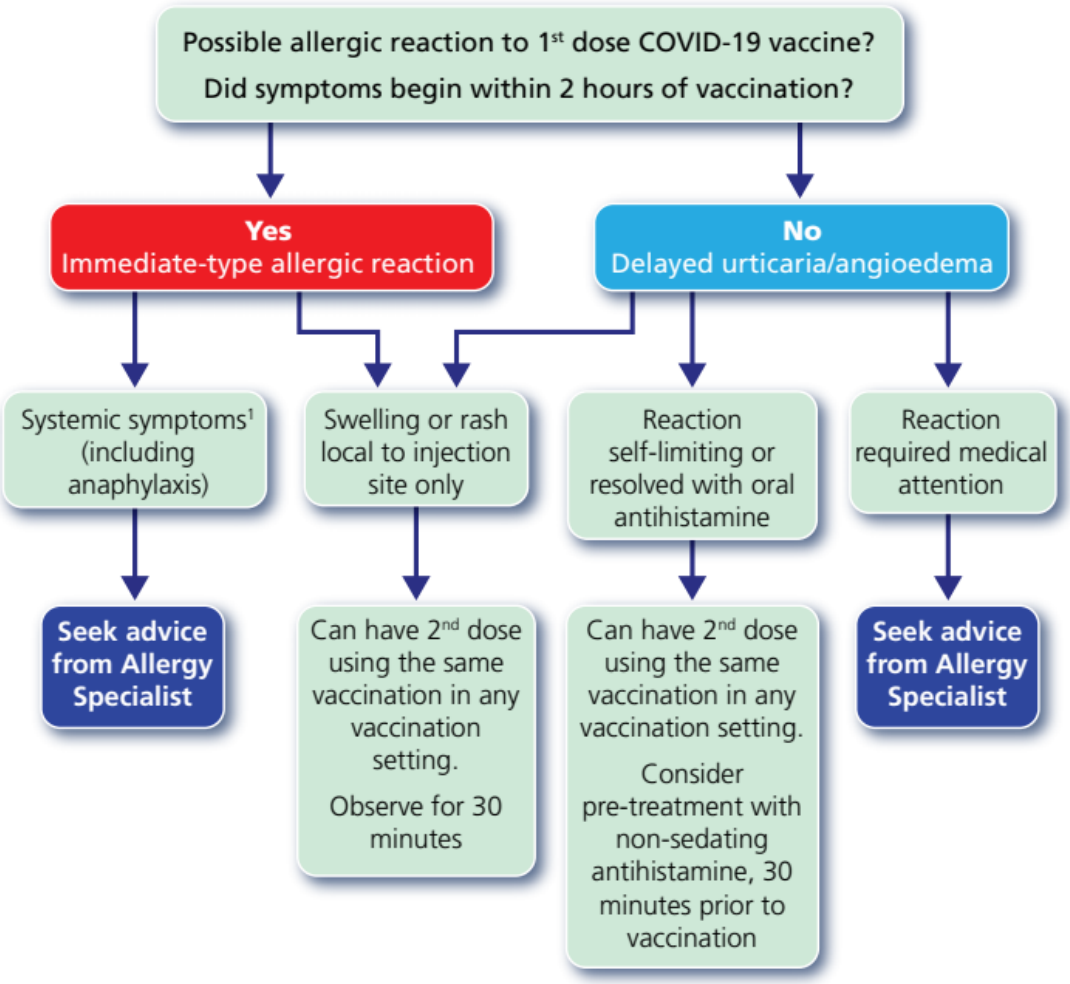
Medical history: contraindications and precautions

- For all patient groups, those whose medical history contains absolute contraindications found within the vaccine's Summary of Product Characteristics (SPC) will be excluded from using that particular vaccine and consideration given as to whether other vaccines may be offered at a different time.
- A very small number of individuals have experienced anaphylaxis when vaccinated with the Pfizer/BioNTech COVID-19 vaccine. Following close surveillance of the initial roll-out, the 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 Pfizer/BioNTech COVID-19 vaccine should be monitored for a minimum of 15 minutes. Facilities for management of anaphylaxis should be available at all vaccination sites (see Green Book Chapter 8).

- The British Society for Allergy and Clinical Immunology (BSACI) has advised that individuals who have a reaction to the first dose of a COVID-19 vaccine may be able to receive a 2nd dose of vaccine. Providers should follow the flowchart provided in the Green Book chapter 14a, reproduced below:

Figure: Flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine



- 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.

Preventing multiple vaccinations

To avoid a client receiving a 2nd vaccine on the same visit, please consider the following:

- Review client flow through the vaccination site, and ensure there is a checkout process and that stewards are positioned there to prevent a person from accidentally re-joining another vaccination queue. It is therefore particularly important to ensure there are enough stewards as patients are leaving vaccination rooms.
- Consider additional mechanisms to highlight that a client has been vaccinated, eg, the use of stickers or laminated cards that are handed to stewards on the way out.
- Where possible, consider consenting and vaccinating in the same location (even if done by different members of staff).
- Prior to vaccination, when asking a client if they have received a vaccination in the last 7 days, also specifically check whether or not they have received their COVID-19 vaccination yet today.
- Remember that people may not volunteer this information without being asked specifically, as people often do not question processes in place at the time.
- Particular attention must be given if someone is confused - obtain a collateral history from a relative or carer accompanying them where possible.
- If vaccinating multiple people from the same household, double check that none of them have been vaccinated yet that day, particularly if there are multiple vaccination streams in the vaccination site.

Pregnancy and breast-feeding

- 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. If a woman finds out she is pregnant after she has started a course of vaccine, she may complete vaccination during pregnancy if she is considered at high risk. Alternatively, vaccination should be offered as soon as possible after pregnancy.

- 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.

Further information can be found on the GOV.uk website.

Other vaccinations

- For all patient groups, COVID-19 vaccines should not routinely be given if any other vaccination has been received within the last 7 days, as set out in the Green Book Chapter 14a on COVID-19 vaccination. However, adjacent or co-administration can occur where this would cause delay or reduce access to either influenza or COVID-19 vaccine for certain patient groups e.g. care homes, housebound patients and hard to reach or vulnerable groups.

COVID-19 symptoms

- For all patient groups, COVID-19 vaccines should not be given if to anyone who are suspected or confirmed to have COVID-19 or are awaiting a test result.
- As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen in those who are asymptomatic.

Supporting people to access the vaccine

Under the Equalities Act (2010), people with a learning disability or health condition that has a substantial and long-term effect on day-to-day activities are entitled to reasonable adjustments when accessing health services. This means that steps must be taken to remove or minimise the barriers that individuals with serious mental illness (SMI), dementia, a learning disability or autistic people may face in accessing the vaccine.

Most people with a SMI, dementia, a learning disability or autism will be able to receive their vaccine in the standard way. However, for the minority of individuals where this is not suitable, the reasonable adjustments that are needed should be determined in advance of the vaccine provision and be centred around individual needs. By putting reasonable adjustments in place, it will help to ensure the vaccine is administered to individuals safely and in a way that minimises their discomfort or distress.

Some proposed adjustments for people with SMI, dementia, a learning disability and autistic people can be found at Appendix F. Some individuals may require more substantial adjustments than the ones listed, which may not always be available in local vaccination services/vaccination centres where facilities/resources are limited. Where this is the case, vaccination at home should be considered. In all cases, the priority is to ensure that a person can access the vaccine as quickly as possible while minimising distress.

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 of 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 11th week of the 12-week period (or 77-84 days after the first dose). The National Booking Service requires the second dose appointment to be booked at the same time as the first dose appointment. Community pharmacy providers must therefore ensure that sufficient second dose appointments are available 77-84 days following first dose appointments.

Wherever possible, patients should be advised to attend the same vaccination setting for both doses to ensure that the correct vaccine is available and the second dose is administered within the appropriate timescale. Patients will usually book both first and second appointment at the same time and with the same provider. However, there are some circumstances where it clearly may not be possible for the patient to attend the same setting, eg they have moved house or, in between the first and second dose, they have moved to a new GP practice which is not part of the PCN grouping that administered the first dose. In these circumstances, it would be appropriate for the new provider to administer the second dose. The patient's choice of provider must be taken into account, and they cannot be mandated to attend the same site, and should not be refused a vaccination on that basis.

4.3 Booking and communications

PCN Grouping Providers

General practice providers are responsible under the Enhanced Service for using existing local systems to undertake local call and recall using nationally determined text (available on FutureNHS), identifying and inviting all eligible patient cohorts, as advised by the commissioner, on their registered list to book vaccination appointments.

Patients registered with practices which have chosen not to sign up to the Enhanced Service can be vaccinated by an alternative general practice provider (where there is a written agreement between the commissioner and the PCN Grouping that the PCN Grouping will vaccinate the patients); or any other provider. The patients' registered practice should co-operate with the commissioner to ensure that patients are advised as to where they can access vaccination. National call and recall communications may also direct these patients to the National Booking System so they can secure a vaccination through a community pharmacy-led site or vaccination centre.

Unregistered patients who are eligible for vaccination, and who request a vaccination from a PCN site should be assessed for eligibility and vaccinated. They should not be turned away or signposted elsewhere. See the section on Access in 2.3 for more information.

As part of the booking process, providers are advised to ensure that eligible patients:

- do not have any clinical exclusion criteria for why they should not be vaccinated
- can attend both appointments for both doses of the vaccine within the required timescales.
- require any additional support e.g. access, translation and interpretation, chaperone, etc, and any reasonable adjustments e.g. for people with a learning disability or who may be autistic (see Appendix F); PCNs should prepare their sites to enable support and reasonable adjustments through all aspects of the operating model
- for patients who have not received a call and recall communication e.g. care home staff to bring proof of eligibility/employment if they have it to support a smooth process.
- For care homes, additional actions have been set out in Appendix D, and for housebound patients see Appendix E.

Community Pharmacy Providers

Patients will predominantly book their appointments via the National Booking Service (NBS). However, a number of eligible patients may not be able to use the NBS, or patients may be vaccinated as part of ensuring reduced vaccine waste and community pharmacy-led sites can also undertake local booking under the terms of the LES. In these instances, patients can be vaccinated and added manually to the Outcomes4Health/Pinnacle Point of Care system. Within 2-3 days of that record being created the patient will then be able to book their second dose appointment via the NBS in the same way as any other patient.

Communicating for diversity and inclusion

Providers may wish to work with their commissioner to support their communication approach, to account for the needs of the local population. For example:

- Providing links/videos in different languages when booking in a patient;
- Enabling those non-digital patients access to information/bookings;
- Providing information to local community and faith groups.

A range of resources are available to help improve access to and education around the COVID-19 vaccine across all our communities, such as videos, leaflet translations and infographics in different languages. This includes Doctors of the World translations of COVID-19 information resources in over 60 languages: https://www.doctorsoftheworld.org.uk/coronavirus-information/

Public Health England (PHE) resources are available to sites, including in accessible formats, to help communications with the public. These are frequently updated and can be found here.

PHE has also published a leaflet on the use of human and animal products in vaccines: https://www.gov.uk/government/publications/use-of-human-and-animal-products-in-vaccines

The FutureNHS Communications and Engagement pages also include the following resources:

- An easy read template invitation letter for use by PCN-led sites when contacting people with a learning disability and autistic people, together with an easy read COVID-19 immunisation guide;
- Tips on the COVID-19 vaccination for people with dementia;
- A communications pack to help engagement with diverse audiences.

Further resources are available to help staff provide accessible appointments to ensure people with a learning disability and autistic people in a high-risk group have safe and equitable access to COVID-19 vaccination:

- Covid Vaccine film produced by Skills for People and Learning Disability England
- PHE easy read Covid vaccination leaflet
- PHE easy read What to expect after the vaccine leaflet
- PHE easy read Consent form for adults

Additional training materials for COVID 19 vaccinators and volunteers provide top tips on communicating with people with a learning disability and autistic people and reasonable adjustments that should be considered.

4.4 Arrival and check-in

The designated site should have a process in place to manage patient flow.

Within this process, the patient accessing local vaccination services must be screened to check:

- that they are eligible to be vaccinated under the current cohorts;
- the patient is scheduled for a vaccination by checking their name and address against the booking system records; and
- the patient (when asked) confirms that they do not have any symptoms of COVID-19 (as per case definition), or are not awaiting the results of a COVID-19 test. This must take place before patients access the site building.

Patients with NBS appointments (community pharmacy-led sites only) must also be checked-in on the NBS system. The NBS (Q-Flow) website for vaccination sites has more information, as well as a dedicated user guide.

4.5 Consent and mental capacity

Consent

All patients who are able to give informed consent are required to do so, in order to receive the vaccination. Those being vaccinated should be able to understand, retain, use or weigh, and communicate:

- the anticipated benefits of vaccination in the simplest of terms,
- the likely side effects from vaccination and any individual risks they may run should be addressed, and
- the disbenefits of not consenting to the vaccination.

Chapter 2 of the Green Book states consent must be obtained before administration of all vaccines. This applies where the patient is able to give informed consent. The guidance in this chapter is based both on the current legal position and the standards expected of health professionals by their regulatory bodies.

There is no legal requirement for consent to immunisation to be in writing and a signature on a consent form is not conclusive proof that consent has been given, but serves to record the decision and the discussions that have taken place with the patient or in relevant cases, the person giving consent on a child's behalf.

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.

The informed consent should be recorded (this is a required field on the Outcomes4Health/Pinnacle Point of Care system). The patient should be provided with written information about the vaccination.

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.

Patients who lack the relevant mental capacity

Some people who will be offered the vaccine may lack mental capacity to make decisions about vaccination. This will include some (but not all) people with dementia, learning disabled and autistic people, people with mental health difficulties and people with acquired brain injury. These people, if they are aged 16 or over, are protected by the empowering, decision-making framework set out under the Mental Capacity Act 2005 (MCA).

These legal requirements will be familiar to everyone involved in the care and treatment of these people, as they will be used to considering them for other, similar decisions, including a decision to test a person for COVID-19, or administer the flu vaccine to help protect them from illness over the winter. The principle of best interests decision making under the MCA is the same for the COVID-19 vaccination.

Health care professionals offering the vaccine to someone who may lack the mental capacity to consent should take all practicable steps to support the person to make the decision for themselves.

Where it has been established that the person lacks capacity to consent, a best interests decision should be taken in line with best interest checklist in section 4 of the MCA. This means that the decision-maker must consider all the relevant circumstances, including the person's wishes, beliefs and values, the views of their family where appropriate and what the person would have wanted if they had the capacity to make the decision themselves. Care home staff or other types of carers should plan in advance to ensure that the health care professional administering the vaccine has the information they need to make an appropriate best interests decision about consent, at the right time.

The decision maker should make a record of their best interests decision. Best interests decisions must always be made on an individual basis.

Where appropriate, the person's advocate or those with power of attorney for Health and Welfare should be consulted. If there is a deputy or attorney with relevant authority, then the heath care professional can only give the vaccination if the deputy or attorney has first given their consent. Such consent can only be given if it is in the patient's best interests.

Relevant consent forms, other supporting forms and associated information can be found on the GOV.UK website.

Consent (given by a deputy or attorney with relevant authority in the person's best interests), or a best interests decision by a health care professional to vaccinate, or not, (informed by advance consideration and information gathering undertaken by carers), should be recorded. This is a required field on the Outcomes4Health/Pinnacle Point of Care system. 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.

Additional considerations for care homes and care staff

Further important guidance on consent and mental capacity for care home residents and staff can be found in Appendix D.

Health and social care staff

PHE has provided templates for consent forms and letters for social care staff (working in care homes) and the wider health and social care staff.

Additional considerations for people with SMI, dementia, a learning disability or autistic people

Informed consent

- In order to provide informed consent, people with SMI, dementia, a learning disability and autistic people need to receive information about the vaccine both in advance of and at their vaccination appointment.
- This information should meet individual communication needs, for instance, through providing information in translation, 'Easy Read' versions, visual prompt cards, explanations via video, or verbal explanations. Explanations should use short sentences, repeat key information and avoid jargon. 'Easy read' information and consent forms developed by Public Health England can be accessed here.
- To support people to understand the information and come to an informed decision, time should be taken to explain all the benefits and risks and deal with any queries and concerns. Family members and carers should be engaged early, as appropriate, and provided with relevant information to support them in this role.
- The individual and family members/carers should also be given the opportunity to speak to a health care professional, so they can raise any questions or concerns they have about the vaccine in order to make an informed decision.
- Discussions ahead of vaccination appointments should also be used to check whether the person has any contraindications to vaccination and to identify any medical, communication or support needs that the person may need addressed to attend the appointment and to receive the vaccine

Mental capacity

- When determining if someone with SMI, dementia, learning disability or autism has mental capacity, it is important that information is provided in a way that the individual can understand and that the person is supported to communicate their decision (e.g. in writing, verbally, signing or non-verbally). For people with fluctuating capacity, conversations about the vaccine should take place at the optimal time for the person, when they are most likely to be able to demonstrate their mental capacity to decide about the vaccine. If at the point of vaccination, the vaccinator does not think that a person has mental capacity, then a best interests process should be followed.

Declining the vaccine

- If someone has mental capacity, then they have the right to decline the vaccine. They do not need to give a reason.
- Anyone who declines the vaccine should be made aware that they can change their mind at any point and request the vaccine at a later date.

- It is important that when offering the vaccine on subsequent occasions, conversations are conducted with the individual respectfully, recognising that it is the person's right to make their own decision.
- Importantly, the Mental Health Act cannot be used to enforce vaccination as the vaccine does not constitute treatment for a mental health problem. In addition, where someone has mental capacity, restraint must never be used to administer the vaccine.

Individuals without mental capacity to consent

- The information above on 'Patients who lack the relevant mental capacity' should be followed for people with SMI, dementia, a learning disability and autistic people.
- If the person has a valid Advanced Decision (i.e. witnessed, in writing, and stating that it applies even if their life is at risk) to refuse all vaccines, or specifically to refuse the COVID-19 vaccine, then this must be followed.

4.6 Clinical review

The patient must be assessed for their suitability for vaccination following informed consent being obtained.

The principles of The Green Book: Immunisation against infectious disease should be followed as well as COVID-19 vaccine specific guidance.

It is not anticipated that detailed knowledge of the individual's recorded past medical history or allergy history will be essential to allow for safe decision making about vaccine administration. However, access to the Summary Care Record will be available in all settings. Some conditions may increase local side effects, i.e. bruising and anticoagulants/clotting disorders, but not be inherently unsafe.

4.7 Delivery of vaccination

See section 3 for signposting to information about preparation of COVID-19 vaccines.

The patient should be prepared as per usual immunisation protocols and infection prevention and control procedures, and the vaccine delivered as advised by the vaccine manufacturer and as per PHE vaccination guidance for healthcare practitioners.

4.8 Post-vaccination observation

Post-observation periods should follow normal arrangements for observation after vaccination and pharmacovigilance, as set out in the Green Book. Information relating to specific vaccines will be provided as it becomes available:

For the Pfizer/BioNtech COVID vaccine, recipients should be monitored for a minimum of 15 minutes after vaccination, with a longer observation period when indicated after clinical assessment, as set out in the MHRA statement and Green Book chapter 14a.

For the Oxford/AstraZeneca vaccine there is no requirement for 15 minutes observation unless this is indicated after clinical assessment or where the patient has experienced an adverse reaction to a previous vaccination dose.

As syncope (fainting) can occur following vaccination, all patients receiving a vaccination should either be driven by someone else or should not drive for 15 minutes after vaccination, nor should the individual operate machinery. This is in accordance with as per PHE vaccination guidance for healthcare practitioners.

Patients should be given a post-vaccination record card (delivered to providers alongside the vaccines) with details of their vaccination (there is also the option to input the patient's email into the Outcomes4Health/Pinnacle Point of Care electronic record system for an electronic copy), and provided with information on the process to follow if they experience an adverse event in the future after leaving the site, including signposting to the Yellow Card service.

The patient should be made aware of possible side effects as set out in the patient leaflets (delivered to providers alongside the vaccines and available online).

The Public Health England (PHE) Immunisation Department is conducting enhanced surveillance of COVID-19 cases in vaccinated individuals in England. Clinicians who are seeing patients face to face are encouraged to report any confirmed cases in partially or fully vaccinated individuals if they tested positive within the preceding 7 days. This provides an opportunity to get early and complete samples from these cases. Further information is available here.

4.9 Records management and data validation

Designated sites must ensure contemporaneous clinical record keeping. Local vaccination services will be required to document the vaccination event into the Outcomes4Health/Pinnacle Point of Care system. Providers can create an input for any patient using a look up from PDS by NHS number or patient demographic details.

The minimum data capture process will be:

1. Patient confirms consent verbally, from which the applicable consent scenarios can be selected

2. Clinical review and screening questions will be prompted from Outcomes4Health/Pinnacle, as well as a notification of flu and Covid-19 vaccination status to enable recording of clinical review.

3. Capture of the vaccination event details through;

    - Manual data entry into system
    - Vaccine data input using barcode scanner

Outcomes4Health/Pinnacle also includes a field to record patient ethnicity and we would encourage all sites and staff involved in recording the vaccination event to endeavour to collect this information from patients. This data will play an important role in helping us monitor and understand vaccine coverage across different groups with a view to targeting interventions towards communities with low uptake in order to reduce health inequalities.

All sites should ensure records within Outcomes4Health/Pinnacle are kept up-to-date as vaccination data is extracted from the platform and shared with NHS Business Services Authority (which manages the payment process on behalf of NHS England) to calculate monthly payments due to providers. More information on payments can be found in our financial guidance on FutureNHS.

5. Appendices

Appendix A: Workforce planning

Guidance has been issued to help PCNs and Community Pharmacy access the National Workforce Supply Routes. LVS sites should consider how best to maintain workforce resilience including by drawing down on additional support.

There is a 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 Ambulance staff and NHS Volunteer Responders.

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. A list of the Workforce Lead Providers for each ICS area is available on FutureNHS.

Given the diversity of models and available staff within the community it is difficult to predict what flow rates might be achieved. The below table presents some of the potential flow rates that could be achieved based on guidance from the Royal College of General Practitioners on mass vaccination for flu.

	Time between vaccinations (Minutes)								
	2	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
1 Vaccinator	200	300	400	500	600	700	800	900	1000
2 Vaccinators	100	150	200	250	300	350	400	450	500
3 Vaccinators	66	100	133	167	200	234	267	301	334
4 Vaccinators	50	75	100	125	150	175	200	225	250

	Estimated time it will take to vaccinate 100 people (minutes)

Workforce skill-mix

The table below presents some suggestions on how designated sites could utilise their workforce to support the delivery of local vaccination services, dependent on the legal mechanism adopted for administering the COVID-19 vaccine(s). It may be appropriate to combine these roles across a smaller number of staff when providing local vaccination services to some sites e.g. care homes. It is recommended that providers review their local staffing and skill mix, including through the use of unregistered vaccinators, available from the National Workforce Supply Routes to enhance local capacity and ensure a sustainable staffing model for the vaccination programme.

Roles	Task
Registered Health Care Professional (HCP)	Obtaining informed consent (and vaccinating as required)
	Diluting /Drawing up vaccine
	Directing and managing any medical emergency
Non-Registered Healthcare providers	Diluting/Drawing up vaccine Vaccination when appropriately trained, supported and supervised by a clinician. (This will be under a national protocol or under a PSD if supervised by a prescriber).
	Infection control / additional cleaning and support of clinical staff
Administrative support	Assistance with record keeping
Reception support	Meeting and greeting people, arrival symptom check

Patient marshalling, car parking and advocacy	Directing those being vaccinated, maintaining flow and social distancing Support to those requiring additional assistance

Appendix B: Health inequalities and inclusion health

The Joint Committee on Vaccination and Immunisation has provided as Annex A to their Priority groups for coronavirus (COVID-19) vaccination guidance, advice on COVID-19 vaccinations and health inequalities. Public Health England has produced inclusion health guidance which will support NHS staff to make services – including vaccination services – as inclusive as possible to promote the health and wellbeing of individuals in inclusion health groups.

COVID-19 has had a disproportionate effect on certain sections of the population – including older people, men, people living in deprived areas, BAME groups, those who are obese and those who have other long-term health conditions, mirroring and reinforcing existing health inequalities, as highlighted in the PHE review of disparities in risks and outcomes and the PHE report on the impact of COVID-19 on BAME groups. Furthermore, the long-term economic impact of the pandemic is likely to further exacerbate health inequalities. Within the priority groups set by JCVI, designated sites will need to consider what reasonable steps they take to target uptake and should collaborate with their commissioner, local voluntary and community organisations to make sure those who are most excluded have access to local vaccination services. Additional patients have been identified by COVID-19 population risk assessment. This has been used at a national level to identify additional groups of patients with specific multiple risk factors which, when combined, may put them at a similar risk to those who are clinically extremely vulnerable to severe outcomes. As a precautionary measure this group will be added to SPL on advice of the CMO, to enable them to be prioritised for vaccination. Further details are available in the letter of 15 February here.

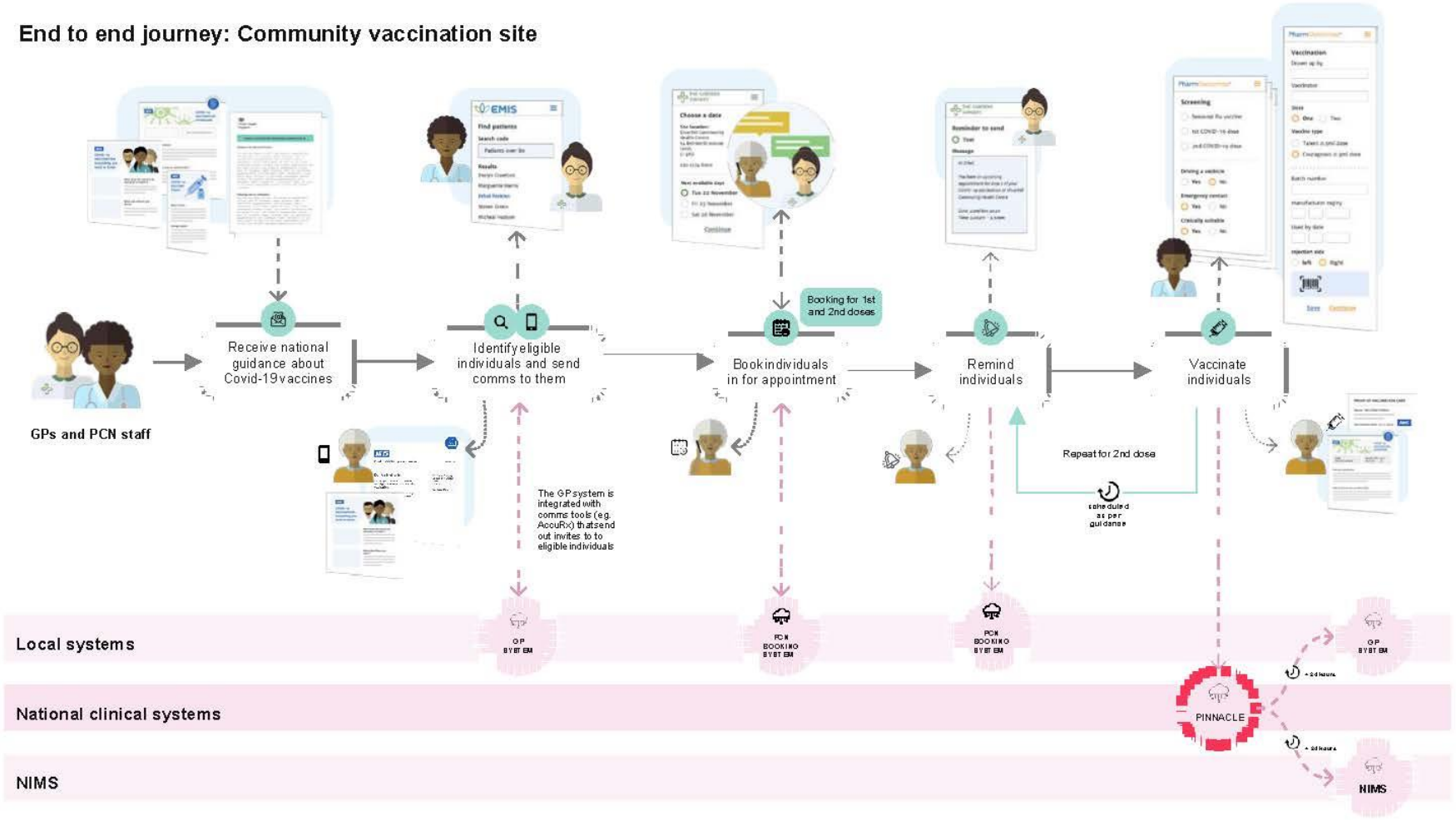
National action to enable and locally deliver community activity and engagement to support COVID-19 vaccination access and uptake is described in this letter of 24 February 2021. This builds on the Government's vaccine uptake strategy.

People experiencing homelessness: During the pandemic some of your registered patients may have been displaced out of area and/or a group of homeless people relocated into your catchment area due to measures applied by local authorities. Practical resources are available from the Faculty of Inclusion Health and the FutureNHS Collaboration space (contact FutureNHS for access).

The Home Office may have set up initial accommodation for asylum seekers in your area who may need access to (and have a right to register for) local vaccination services. PHE has published advice on healthcare for refugees and migrants. Doctors of the World can provide specialist advice on working with asylum seekers and refugees.

Gypsy, Roma and Traveller communities face some of the most severe health inequalities and poor health outcomes in the UK. Friends, Families and Travellers has a service directory on its website, and relevant information on COVID-19.

Appendix C: Visual end to end journey for local vaccination services (PCNs)



Appendix D: Operating model for providing local vaccination services in care homes

This section should be read in conjunction with all other content in this SOP, and provides further guidance and advice specific for roving vaccinators attending care homes.

It is recommended that PCN groupings identify care home sites via the PCN's existing care home clinical leads (required under the PCN DES) and then arranges to visit to the care home site to provide vaccination for all eligible cohorts.

Community Pharmacy Providers may be asked by commissioners to undertake vaccinations in care home settings where they identify that a gap exists in likely provision.

As a principle, providers should seek to minimise the number of unnecessary visits to care homes to mitigate potential risk to residents. A minimum 4 visit schedule is recommended;

- Dose 1 - all (or most) residents and staff on site
- Second visit - to capture staff or residents who were unavailable on the day and who have not had their 1st dose
- Dose 2 - vaccinations offered to residents and staff within the 77-84 day window following the 1st dose. New residents and staff who have not had their 1st dose should also be offered the vaccine at this visit
- Fourth visit- to capture outstanding 2nd doses one week later.

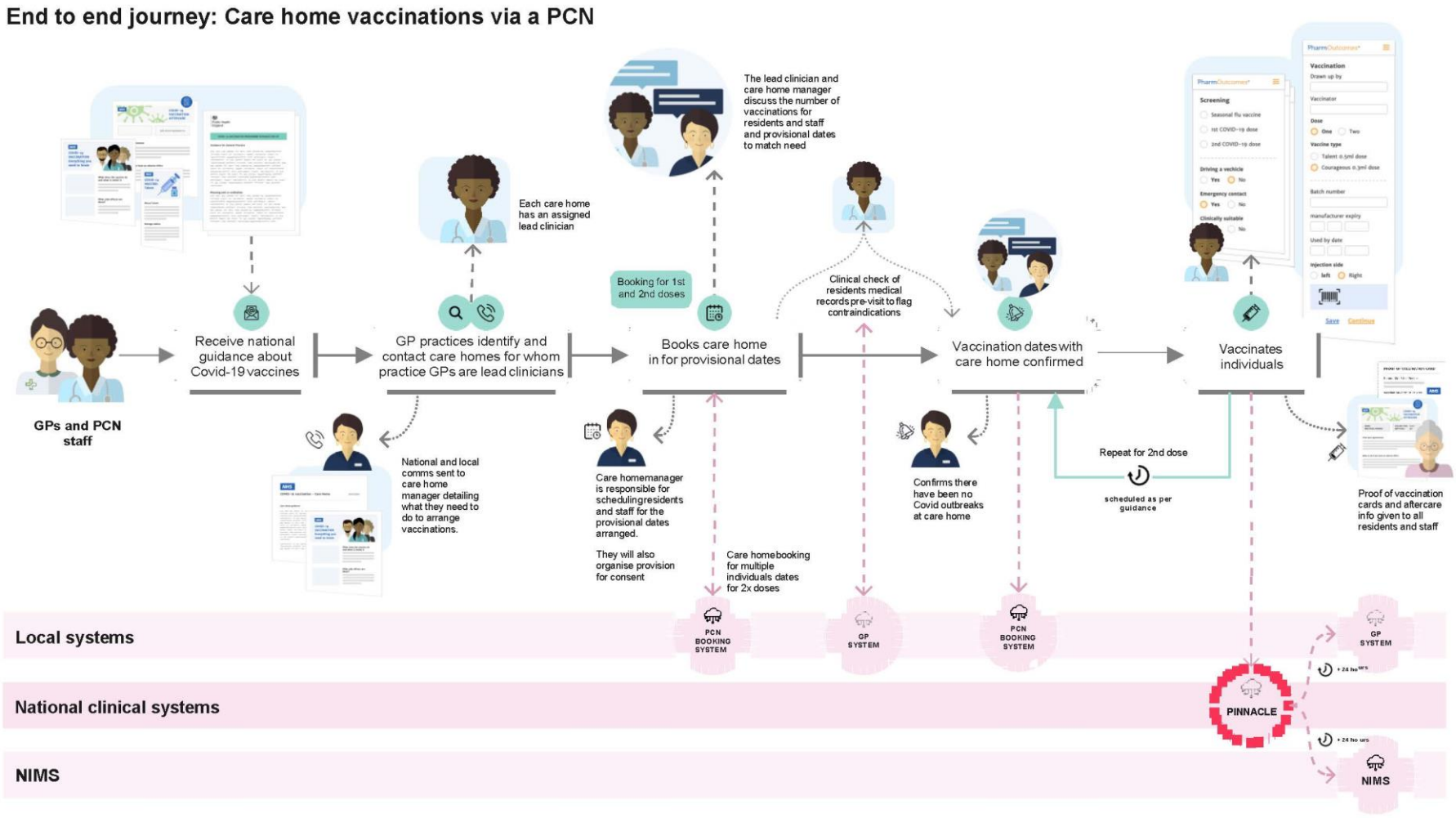
The need for a second visit will depend on individual care home circumstances and there should be a pragmatic approach to these decisions following discussion between the care home manager and vaccination team. For example, where there are both residents and staff members who have yet to be vaccinated, then a second visit would be needed. However, if there are only one or two staff members remaining to vaccinate, then a second visit from the roving team may not be appropriate. The most important principle is that there should be an open and collaborative channel of communication between individual care homes and vaccination teams.

A regular follow up visit until mass population coverage has been achieved may be required, providers should agree an ongoing rolling process with care homes.

PCN groupings should also ensure that consideration is given to the vaccination of eligible older patients who may be living in Learning Disability residential care homes/settings and social care staff working in those settings.

The following sections include the visual end to end journey for care homes, a practical checklist setting out the key steps and recommended timescales, which links to detailed guidance and advice to support providers to ensure the safe and efficient delivery of vaccinations to care home residents and staff.

Visual end to end journey for care home vaccinations (PCNs)



Checklist for Care home vaccinations operating model

Days before visit	Checklist of actions to deliver local vaccination services (LVS) to care homes
Day 5	• Care home engagement - Care homes agree to support PCN with consenting and prepare site • Vaccination team – commission vaccination team aligned to care home requirements • **Vaccine** provision – Order vaccines suitable for roving vaccinations • **COVID-19 Test preparation** – PCNs have PCR/LFT prior to visiting care homes
Day 4	• **Consent grouping** – residents grouped: 1) Have capacity, 2) require LPA, 3) Best Interest decision • **Information about COVID-19 vaccine** - Care homes share information with relatives and residents • **Clinical Review** – Check medical records of residents for allergies and other exclusions • **Care staff vaccinations & reserve list** – Care home staff scheduled for vaccinations
Day 3	• **Consent discussions** - Care homes continue consenting discussions and document across the 3 groups • **Roving SILs** – Check PCN has stock of all consumables / IT / resuscitation equipment and medicines • **Cold chain preparation** – Ensure freezer in place for freezing gel packs. Gel packs must not be stacked. • **Vaccine transport container** - Make the container for securing vials for transportation in cool box(es)
Day 2	• **Consent assurance** - Vaccinator consults relatives to confirm consenting decisions across the 3 groups • **Vaccination training** – Check all vaccination team members have completed relevant training • **Cold Chain training** – Team run-through of cold chain process (supported by CCG lead Pharmacist) • **SOP walk-through** – Confirm all vaccination team members are prepared and understand the SOPs

Day 1	• **Review patient schedule** – Check clear which residents are cleared and call in reserve list as needed • **Site assurance** - Sign off care home configuration for vaccine preparation/delivery and COVID-secure • **Final Equipment review** – Check all roving SILs, cold chain items, resuscitation items, and **IT** equipment. • **COVID-19 test results** – Check all members of vaccination team have a negative test result to COVID-19.

LVS day	• **Final care home check** - Contact care home to re-confirm readiness
	• **Cold chain validation** – Complete temperature validation on cool box:
	• **Travel to care home** - transport cool box, roving SILs, resuscitation items, IT, consumables, etc
	• **Site set-up** - Set-up in designated area of care home and complete final check on residents.
	• **Implement LVS** – Reconstitute and deliver vaccines, as per section 4 of this SOP (where applicable):
	  ○ Mobile residents attending vaccine station / designated area of care home
	  ○ Residents unable to leave rooms
	  ○ Care home staff and reserve list
	• **Session conclusion -** Debrief with care home and vaccination team, pack-up, and return to the PCN site.

Care home engagement

PCNs should engage with their care home(s) as soon as possible to begin joint planning; this is particularly important to assess how the care home staff will be able to support this operating model accounting for different types of homes and how they may be resourced and operated. The extent which a care home can involve themselves in this process will have a significant impact on the resource requirements of vaccination teams and the safety of residents.

On 4 December, the Minister for Social Care wrote to all local authorities and care providers advising them on what to expect and what actions care homes could take in supporting NHS providers to deliver vaccinations to care home residents and staff. The Chair of the Social Care Sector, Medical Director of Primary Care, and Deputy Chief Medical Officer has also produced this video to answer questions about the vaccine for the care sector.

Site configuration

Care homes should be encouraged to consider site configuration to enable an appropriate area for vaccine preparation and delivery maintaining patient confidentiality and privacy, applying all guidance set out in section 2.3 of this SOP.

Care homes should ensure the site set-up includes having a sensible place for the cool box (minimising risk to the cold chain), a sterile area for dilution / reconstitution of vials, an area for administering vaccines, and an area and system for post observation of residents.

Where possible, residents should be vaccinated close to where the vaccine is prepared to minimise movement of the vaccine following reconstitution (i.e. residents should move to vaccinators rather than vaccinators moving around care homes).

Influenza vaccine at care homes

PCNs should encourage care homes to maximise staff and resident through-put for seasonal flu vaccination ahead of the COVID-19 vaccine deployment, to mitigate the increased mortality rate resulting from dual infection and to optimise COVID-19 vaccination deployment (as there should be 7 days between flu vaccination event and covid-19 vaccination event). Employers should seek to confirm that staff have

scheduled and received their flu vaccination at least 7 days prior to the care home visit.

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, with the aim of achieving high uptake as rapidly as possible. 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 is available here.

Vaccination team

The PCN should establish a roving vaccination team, considering its available skill-mix and any specific requirements of the care home. We recommend the following set-up:

- 2 x vaccinators (1 lead & 1 support)
- 1 x vaccine manager (nurse or pharmacist leading vaccine reconstitution and cold chain management
- 1 x Post vaccine observer (Paramedic or nurse)
- 1 x team admin (admin support as required)

The roving vaccination team should be adjusted as required to account for the different level of support care home staff can offer (e.g. advance planning for consent), the configuration of the care home, and the number of residents. With this set-up (and subsequent steps below completed), as a guide a single vaccinator may achieve 30 vaccinations per half-day (i.e. 2 vaccinators: 60; 4 vaccinators: 120).

Training

See section 2.4 for resuscitation training and section 3.1 for vaccination training in this SOP.

Vaccine provision for care homes

The Oxford/AstraZeneca vaccine should be used in the first instance for care home visits given its more flexible handling properties.

Information on how to access other types of vaccine will be provided as soon as the details are available.

COVID-19 testing programme

Providers should ensure PCN staff testing is in place and all members of the vaccination team should take a PCR / LFT test prior to visiting care homes to mitigate risk of PCN staff testing positive on arrival (which could have implications for the whole vaccination team leading to disruption of the planned session and potential vaccine waste). LFT kits are available for all parts of primary care and ordered via PCSE. A Standard Operating Procedure on lateral flow antigen testing in primary care, FAQs and an NHS staff guide to self-administering the test can be found here.

Any PCN staff testing positive should be excluded from visiting care homes, and a risk assessment should be completed to assess what other staff may have come in contact and require self-isolating. If PCN staff cannot reasonably demonstrate no contact with COVID-19 positive colleagues, they must be excluded from the care home visit.

Care homes should also be encouraged to implement regular testing of care home staff and residents prior to vaccination teams visiting.

Consent and mental capacity for care home residents

Consent grouping

Care homes can support PCNs by using their local knowledge of their residents to complete some provisional assessment and group residents into three categories:

- Those who are likely to have mental capacity to consent
- Those who have an attorney appointed under a Lasting Power of Attorney (LPA) or a court appointed deputy who has authority to make this decision on the person's their behalf
- Those who may require a best Interest decision made on their behalf.

This will help both care home and PCN staff to organise resources between them and allocate workforce best placed to manage residents within each of these groups.

PCNs responsible for providing local vaccination services to care homes should encourage care home providers to support their resident patients by beginning informal conversations regarding consent with relatives and identify those who will consent (where the patient does not have capacity to consent); formal consent will only be possible when the vaccine type is confirmed for deployment at this site and informed consent may be given 4-5 days prior to the local vaccination service attending the care home (subject to the specific characteristics and requirements of each type of vaccine being used at this site).

Consent discussions

It is important to recognise that residents in care homes must be treated as individuals and that a decision on vaccination should be made on the basis of informed consent, where an individual has the capacity to make the decision around vaccination. Care home staff or other types of carers should plan in advance and share information about the vaccine, what administering the vaccine will involve, and when it will happen, with the person.

As this is a new vaccine, steps must be made to provide the information about the vaccine to enable a decision to be made. The clinical lead role can support the care home in delivering the information required to make the decision and support the consent process.

Care home providers should keep an up to date register of residents requiring vaccination and arrangements can then be made with the PCN for a care home vaccination visit. Based on information gathering undertaken in advance, care home staff and other types of carers should present health care professionals administering the vaccine with all relevant information needed to assess the person’s relevant mental capacity at the right time. The capacity assessment and vaccination decision should be specific to the person and recorded.

Consent assurance

Health care professionals administering the vaccine will be best placed to assess if the resident has relevant mental capacity to consent to the vaccination themselves, and if they do not, take the final best interests decision, on behalf of the person,

whether or not to vaccinate (unless there is an attorney or deputy with relevant authority). They will be trained to discharge these duties under the Mental Capacity Act 2005.

The decision maker must consider all the relevant circumstances when making the best interests decision on behalf of the person. Care home staff or other types of carers should plan in advance to ensure that the health care professional administering the vaccine has the information they need to make an appropriate best interests decision about consent, at the right time.

Where practicable and appropriate, the PCN should consult, for example, the person's advocate and those with power of attorney for health and welfare in advance (unless the attorney or deputy has relevant authority, in which case they will need to provide consent to the vaccination in the person's best interests). They should also consult the person's family if practical and appropriate. Relevant consent forms, other supporting forms and associated information can be found on the GOV.UK website.

Information about COVID-19 vaccines

Care homes should be advised by the PCN which vaccine candidate will be deployed, what the anticipated vaccine characteristics are and any guidance in relation to reactogenicity. Providers are advised to then give consideration to this information when scheduling vaccination to mitigate any potential impact on operational capacity and delivery. Normal illness can occur in the population that won't be a reaction to the vaccine but is likely to be attributed to the vaccine because of proximity to having the vaccine. PCN Clinical Leads (under the Enhanced Health in Care Homes DES) should be available for advice.

Clinical review

The PCN clinical lead / clinicians should review medical records of each resident for allergies, whether medically fit or have any other exclusions for why they shouldn't receive a vaccination. More information can be found in section 4.5 of this SOP. PCNs may need to allocate a number of staff for clinical review across GP practices within the PCN grouping to ensure all residents patient records can be accessed.

PCN Clinical Leads should also be consulted to consider any other useful clinical information about residents within the care home.

Care home staff vaccinations and reserve list

Both care home staff and residents are eligible for a vaccination as they are in priority group 1 and therefore care home staff should be scheduled for vaccinations as well as residents. PCNs should encourage care home providers to consider how to maximise staff uptake of the vaccination through targeted conversations by line managers and with teams, using the staff and public communications materials.

Conversations should also consider any employer support to access vaccination via other sites (such as travel time or mileage) for staff not present onsite for scheduled visits. Care home staff will also be able to access vaccinations at the designated site(s) of the PCN grouping leading the vaccination of the Care Home where they work, via their own registered GP practice (if in a different PCN grouping), a mass vaccination site or any other local provider offering vaccination e.g. Community Pharmacy.

Under the Enhanced Service Specification, a PCN grouping is able to vaccinate and claim payment for vaccinating both care home staff and frontline practice/PCN staff who are registered with practices outside of the PCN grouping.

Reserve Lists
PCN designated sites should also consider when planning their visit, that after all efforts to vaccinate patients and care home staff, any residual supply of vaccine are used to vaccinate care home or PCN staff who are on site, particularly those who have been identified at highest risk of serious illness from COVID-19, e.g. have a plan for using residual vaccine to minimise risk of vaccine waste.

Please note: the following section relates to the Pfizer/BioNTech vaccine and Oxford/AstraZeneca vaccine. Details relating to further vaccines will be provided as soon as they are available.

Cold chain management

PCNs should follow the relevant vaccine SPS SOPs. The GP or clinical lead must be familiar with the relevant legislation (see Chief Pharmaceutical Officer's letter) and be sure that all those involved in storing, handling, preparing and administering the vaccine are competent to do so.

Cold chain preparation

PCN sites will be provided a freezer for cooling of gel packs. Note vaccines should under no circumstances be placed in the freezer. Gel packs should not be stacked within the freezer and spread across shelves.

On initial instillation of the roving cold chain, the freezer must be active for 24 hours before use. In addition gel packs require 24 hours cooling before use. Therefore PCNs should prepare for 24 hours (freezer) + 24 hours (gel packs) = 48 hours for cold chain preparation.

Cold chain training

The PCN should liaise with their CCG Lead Responsible Chief Pharmacist should they require further training on cold chain management.

Cold chain validation

PCNs should (with pharmacist support) complete temperature validation on the cool box to ensure consistent and reliable temperature control can be achieved. The following steps may be helpful in enabling this:

- Gel packs are removed from the freezer and left to settle at room temperature briefly (remove any ice)
- Gel packs can then be placed in the cool box and monitored for 90 minutes to stabilised temperature at 2-8 ^{O}C
- Once confident the temperature control has been established, the PCN may transfer vials to bag, label, and placed into vial transport containers to secure for transport.

Cool boxes must be demonstrated and validated to be able to keep vaccine between 2 and 8^{O}C. Validation is dependent on:

- Load pattern
  - Ice or chilled blocks (including chill method to ensure fully chilled)
  - Positioning in the cool box
  - Type of cool box
  - Number of vaccine vials in the cool box
- Journey/storage time
- Maximum ambient temperature

- Number of times cool box is opened during use, and duration of opening

Validation can be performed centrally (with dataloggers) using a simulated “worst case” scenario, for specific cool box types. It is recommended that real-life monitoring is performed during initial phases of roving vaccinations using a max/min datalogger with readable display.

Validation cannot be extrapolated between different types of cool boxes.

Vaccine cold chain properties

Pfizer/BioNTech:

MHRA has confirmed that the swift transfer of thawed vaccine from the PCN sites fridge (where is stored at 2-8 ^{O}C) to a validated cool box, under the control of a healthcare professional and subject to appropriate SOPs, is acceptable, in the absence of data from Pfizer**/**BioNTech to suggest adverse impact on the vaccine. The time out of the temperature-controlled environment should however be kept to a minimum.

The vaccine must be kept between 2 and 8^{O}C and not allowed to freeze (ice crystals may form <2^{O}C). Once 8^{O}C is exceeded, vaccine must not be transported further and must be diluted for use within 2 hours (followed by 6 hours post-dilution storage at room temperature).

Oxford/AstraZeneca:

Distribution as a part of deployment can be controlled at 2-8 ^{O}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^{O}C within its shelf life and at ‘room temperature’ <25 ^{O}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 ^{O}C and 25 ^{O}C during the in-use period. More information on movement of this vaccine can be found in our 7 January letter and position statement for the vaccination of care homes using COVID-19 Vaccine Oxford/AstraZeneca.

Visual end to end journey of cold chain

Prepare a cool box for transport at 2-8°C

Cool boxes must be suitable for the duration of use. They must be prepared according to the manufacturer's instructions.

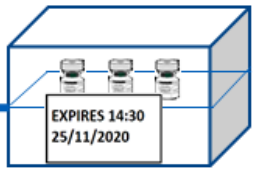
Position the cool box as close as possible to the fridge

Select and pack the required number of thawed vials

- Work quickly to minimise exposure of the vaccine to room temperature.
- Keep fridge door openings to a minimum

Label with:

- contents
- expiry date / time (from outer carton from which the vials have been removed)
- allowed journey time



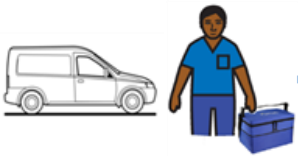
The vials must be securely held in an upright position to minimise movement in transit, and should be protected from light.

Pack the new vial container into cool box

The cool box packing pattern should follow the manufacturer's instructions.

- minimise movement or agitation of the vials
- frozen ice packs must not come into direct contact with the vaccine.

Transport to the end user location



Transit time - MHRA Conditions of Authorisation must be followed:

Pfizer/BioNTech:

- two journeys each up to 6 hours or; one journey up to a maximum of 12 hours

Oxford/AstraZeneca:

- Multiple journeys permitted; once vial is punctured, use within 6 hours

Vaccine transport container

PCNs are required to prepare locally a vaccine transport container which will:

- Secure vials to minimise movement during transport in cool boxes
- Ensure there is no direct contact between vials and gel packs.

Examples of vaccine transport containers which have been used so far are polystyrene packing material and plastic boxes.

Post vaccine observation and adverse reactions

The registered GP Practice would normally be the first contact for advice around adverse reaction. The PCN clinical lead under the EHCH DES may be updated at the next care home round re the adverse reaction. If there is any vaccination reaction, then the care home could use homely remedies policy to be able to treat e.g. paracetamol.

Further information on post vaccine observation and record keeping can be found in section 4.7 and 4.8 of this SOP.

The information in this section relevant to further vaccines that become available will be published when details are confirmed.

Appendix E: Operating model for providing local vaccination services to housebound patients

This section should be read in conjunction with all other content in this SOP, including Section 4, which includes the core operating model, and Appendix D, which includes guidance and advice (eg cold chain management) which will apply for roving vaccinators attending patients own homes.

PCNs will need to consider consulting the community teams for local knowledge, and on how they can offer local vaccination services to patients living in the community who usually receive treatments at home and are generally classed as housebound i.e. they are unable to leave their home at all or require significant assistance to leave the house due to illness, frailty, surgery, mental ill health or nearing end of life.

In some circumstances, it may be possible to arrange for the patient to visit the PCN site, with support from community teams, family and carers. Where this is not possible, PCNs will need to arrange to visit the patient at their own home.

Community Pharmacy Providers may be asked by Commissioners to undertake vaccinations for housebound patients where they identify a gap exists in likely provision.

Additional funding: An additional supplement of £10 per visit to a housebound patient is available. Further details are in our letter of 4 February 2021.

Vaccine: The Oxford/AstraZeneca vaccine is recommended for home visits and our 7 January letter and this more detailed position statement provides guidance on the movement of this vaccine. There are no concerns from a movement stability perspective of transporting the vaccine from house to house to support housebound patients. The vaccine should be stored at +2 to 8°C until first use. After the vial has been punctured, the vaccine should be used as soon as practically possible and within 6 hours. The vaccine may be stored between 2°C and 25°C during the in-use period.

However there are infection prevention and control considerations:

- Ensure existing local guidance on standard infection prevention and control precautions is followed. This will include hand hygiene with the addition of a staff requirement to wear a fluid resistant surgical mask.
- In addition, after vaccination, decontaminate the vial and secondary packaging using an alcohol wipe rather than a detergent wipe before putting it back into the vaccine porter (/bag used to carry the vaccine) for onward transport in view of the unknown risk from other infectious pathogens within the environment in the home. The vaccine porter (/bag used to carry the vaccine) should only be decontaminated leaving the home if there is contamination or if the person in the household has a known infectious pathogen.
- As standard practice for this vaccine, swab the vial septum with an alcohol swab prior to every dose withdrawn and leave to dry for 30 seconds.

SILs: Ensure vaccinator teams have all necessary roving SILs for their home visit.

Consent: Follow guidance set out in section 4.5 and Appendix D of this SOP; additional preparation may be needed to support those who live alone or those who lack mental capacity, before vising the patient's own home.

Clinical review: Consider completing an initial clinical review to assess the patients suitability for vaccination prior to visiting housebound patients if possible; this should be repeated prior to vaccination as set out in section 4.6 of this SOP.

Pre-visit checks: Call ahead to check that the person is well and the home visit can proceed, and someone is available to let the vaccination team in. Ask if someone can open windows to improve ventilation, in advance of the vaccination team arriving, where possible.

Home visit: Follow IPC guidance as per section 2.6 of this SOP, donning the appropriate PPE before accessing the home, and follow guidance on social distancing. On leaving the patient's home, PPE should be removed and disposed of in line with Section 3.3 of this SOP.

Post vaccine observation and adverse reactions: Further information on post vaccine observation and record keeping can be found in section 4.7 and 4.8 of this SOP. The roving vaccination team should record in Outcomes4Health/Pinnacle during the visit, the 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.

Patients and/or their carers should know who to contact if they are concerned about any effects that may be experienced after the vaccination. In most cases, this is the patient's own GP.

Appendix F: Reasonable adjustments for people with SMI, dementia, a learning disability and autistic people

Under the Equalities Act (2010), people with a learning disability or health condition that has a substantial and long-term effect on day-to-day activities are entitled to reasonable adjustments when accessing health services. This means that steps must be taken to remove or minimise the barriers that individuals with SMI, dementia, a learning disability or autistic people may face in accessing the vaccine.

Most people with SMI, dementia, a learning disability or autism will be able to receive their vaccine in the standard way. However, for the minority of individuals where this is not suitable, the reasonable adjustments that are needed should be determined in advance of the vaccine provision and be centred around individual needs. By putting reasonable adjustments in place, it will help to ensure the vaccine is administered to individuals safely and in a way that minimises their discomfort or distress.

Some proposed adjustments for people with SMI, dementia, a learning disability and autistic people can be found below.

People with a severe mental illness (SMI)
Though many people with SMI may be able to attend and receive vaccinations in a similar way to anyone else, adjustments should be considered, where needed, in consultation with the person themselves and their family/carers. The examples of reasonable adjustments below apply to community settings:

- Inviting the person to attend their vaccination appointment using varied modalities, including telephone, letter and text message.
- Scheduling the vaccine appointment at a location that is familiar to the person or they feel confident travelling to (where feasible).
- Offering vaccine appointments flexibly at various times of day. For instance, some people may prefer appointments later in the day due to the effects of medication earlier in the morning.
- Providing reminders about appointment times and informing a family member/carer about when the vaccine is due to be given (with the person's consent).
- Providing repeat reminders that two doses of the vaccine are required in all communications.
- Taking the time required to carefully explain information about the vaccine and to listen fully and respond to the person's questions and concerns.
- Allowing a family member/carer, or someone else who knows the person well (e.g. a care coordinator) to accompany the person at their appointment, to support them to understand information and provide reassurance.

People with SMI living in the community may also benefit from tailored outreach and support. A survey by Rethink showed that people with SMI may have concerns that impact the likelihood of them receiving the vaccine, including concerns about

side effects and the medical risks of the vaccine, worries about potential interactions the vaccine might have with their existing medication, and difficulties getting to a vaccination centre due to their mental health.

Mental health providers and voluntary and community sector organisations can play an important role, working in partnership with primary care, to increase uptake of the vaccine among individuals with SMI. Examples of good practice to increase uptake include:

- Delivering proactive and targeted outreach to people with SMI who may struggle to respond to their vaccination invite. This outreach could include:
  - Proactive contact via telephone / in-person visit to those people who may struggle to access vaccine independently.
  - Sharing further information about the vaccine and myth-busting.
  - Offering conversations to people with SMI and their carers to address their fears and concerns.
  - Offering peer support to attend appointments.
- Primary care colleagues, including the new social prescribing link workers, are well placed to deliver this outreach and support function, as would voluntary and community sector partners who are already in contact with their local communities and can draw on existing, trusted relationships.
- In parallel, community based mental health teams can support vaccine uptake by:
  - Asking patients at appointments about whether they have accessed the vaccine yet and providing them with information and support to make an informed choice.
  - Proactively reviewing caseloads to identify people who may struggle to respond to their vaccination invite letter or attend their vaccination appointment and offering them support from a voluntary and community sector partner, primary care social prescribing link worker or peer support worker.
  - Offering an appointment to receive the vaccine directly from the mental health service (where the NHS mental health provider is a vaccinating hub and has supplies to facilitate this) in cases where someone might otherwise find it difficult to take up the vaccine.

People with dementia

Around a third of people with dementia live in care homes, with the remainder living in the community. It is important that reasonable adjustments are put in place for those individuals that need them, regardless of setting. Examples of the ways that appointments can be adjusted, include:

- Offering vaccination appointments at a time and place that suits the person, and arranging transport to the vaccination site, where feasible.
- Having dementia friendly signage in vaccination settings and, where feasible, providing suitable seating for people with mobility issues, particularly while waiting.

- Allowing a family member or carer, or someone else who is familiar to the person to accompany them to the appointment and be made aware of all arrangements made.
- Using visual prompt cards and 'Easy Read' information to provide further explanation about the vaccine and process of administration.
- The vaccinator using short, simple sentences and pausing between them to give the person time to hear and ask questions, and providing reassurance throughout the appointment.

People with a learning disability and/or autism

For many people, their learning disability or autism will have minimal impact on their ability to attend appointments and receive vaccinations. However, for those individuals that have specific needs, it is important that local delivery systems personalise and adjust appointments where needed. Examples of the types of adjustments that may be considered, in consultation with the individual and their family/carer ahead of vaccination, include:

- Scheduling the vaccination appointment in a familiar environment, which limits the need to travel where possible, e.g. in a residential care setting, or arranging transport to the vaccination site.
- Allowing a family member/carer and/or a specialist learning disability professional (e.g. a learning disability liaison nurse (in hospital) or a community learning disability nurse) to accompany the person at their appointment, to support them to understand information and provide reassurance. In particular, some autistic people may experience significant anxiety about having the vaccine because they are needle averse or phobic and need extra reassurance from someone familiar to them.
- Taking the time required to carefully explain information about the vaccine and the process of administration, listening fully and responding to the person's questions and concerns. This should be done in a way that meets individual communication needs. For instance, visual prompt cards and 'Easy Read' information may be used, while for some autistic people, online or written information may be most appropriate.
- Offering home vaccination appointments in the minority of cases where a person may become highly distressed or frightened about receiving the vaccine.

Some individuals with a learning disability may also have a health passport which will detail the adjustments that they require to access appointments, alternatively details may be included on their GP record. Where possible required adjustments should be identified in advance of the appointment and reception/support staff should be made aware. Local learning disability services will be able to advise providers of vaccination services about the additional resources and adjustments that are available locally.

For more information about working with people with a mental health problem, dementia, a learning disability and autistic people, and their families, during the

pandemic period, please refer to NHSEI guidance on Patient, carer and family engagement and communication during the COVID 19 pandemic.

Information from The Challenging Behaviour Foundation on Accessibility and reasonable adjustments for individuals with severe learning disabilities whose behaviour is challenging

Information from Dementia UK, including: Useful tips on the COVID-19 vaccine for people with dementia

Information and guidance for family and friends, including frequently asked questions

Information from Rethink Mental Illness on the COVID-19 vaccine for people living with severe mental illness

Appendix G: Operating model for providing local vaccination services in residential settings, or settings of multiple occupancy

This section should be read in conjunction with all other content in this SOP, including Section 4, which includes the core operating model, and Appendix D (Operating model for providing local vaccination services in care homes), which includes guidance and advice (e.g. cold chain management) which will apply for roving vaccinators providing LVS in residential settings.

As set out in our letter of 13 February, PCN groupings, and in some cases community pharmacies when requested by NHS England, will need to deliver vaccinations in residential settings, such as care homes for people with learning disabilities or mental health problems, or hostel/hotel accommodation for the homeless, where it would not be possible for these patients to attend vaccination sites. PCN Groupings should work with CCG, ICS, local authority and other partners to establish the most effective ways to serve all of these residential settings and specific groups and determine the most appropriate vaccination delivery model for them.

Note that NHS England guidance on the definition of JCVI cohort 6 (in Annex B of our letter of 13 February) explains that this group includes younger adults (i.e. 16-65 year olds) in long-stay nursing and residential care settings.

The Enhanced Service for General Practice, subject to commissioner approval, allows a PCN Grouping to vaccinate eligible patients registered with another PCN Grouping in a residential setting e.g. care home for people with a learning disability.

Additional funding: An additional supplement of £10 for each vaccination administered to eligible residents and staff in these settings, on top of the £12.58 Item of Service fee is available. Further details are in our letter of 13 February 2021.

Vaccine: The Oxford/AstraZeneca vaccine is recommended for visits to residential settings and our 7 January letter and position statement on the vaccination of care home residents using AZ provides guidance on the safe and aseptic movement of this vaccine and should be followed.

SILs: Ensure vaccinator teams have all necessary roving SILs for the visit to the residential setting.

Consent: Follow guidance set out in section 4.5 which includes a section on additional considerations for people with SMI, dementia, a learning disability or autistic people. Also follow the guidance on consent in Appendix D of this SOP.

Clinical review: Consider completing an initial clinical review to assess the patient's suitability for vaccination prior to visiting the residential setting if possible; this should be repeated prior to vaccination as set out in section 4.6 of this SOP.

Post vaccine observation and adverse reactions: Further information on post vaccine observation and record keeping can be found in section 4.7 and 4.8 of this SOP. The roving vaccination team should record in Outcomes4Health/Pinnacle during the visit. 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.

Patients and/or their carers should know who to contact if they are concerned about any effects that may be experienced after the vaccination. In most cases, this is the patient's own GP.

Appendix H: Operating model for providing temporary vaccination clinics

This section should be read in conjunction with all other content in this SOP, including Section 4, which includes the core operating model for LVS deployment in community settings, and our letter 'Further opportunities for PCN and Community Pharmacy COVID-19 vaccination sites to partner with community venues to delivery temporary vaccination clinics'.

To help improve patient access, in particular to maximise take up of the vaccine in communities or among groups with relatively low coverage, PCN groupings and Community Pharmacy Contractors can administer vaccines from locations other than those which have been specifically designated for COVID-19 vaccination in specific circumstances as set out in guidance. Our letter of 7 January outlining the additional operational flexibilities offered by the Oxford/AstraZeneca vaccine provides the framework for this to take place.

Alternatively, commissioners may wish to deploy dedicated LVS outreach teams for this purpose.

Examples of the kinds of locations where additional temporary vaccination clinics could be temporarily held in order to improve access and uptake are places of worship or community venues.

Local commissioners are encouraged to work with existing contractors to establish temporary vaccination clinics at additional locations where this will help to improve uptake in areas with low coverage.

For PCN groupings, the commissioner will need to approve and confirm the arrangements in writing, including clarifying who the PCN grouping can vaccinate at the temporary vaccination clinic. For example, the commissioner should clarify whether the PCN grouping could vaccinate an eligible patient registered with another PCN grouping at the clinic if they presented.

Community Pharmacy Contractors must be approved by their Regional team Commissioner to provide vaccinations at a venue other than the Designated Site with their LES agreement. NHSEI will amend the LES document to ensure that the nature of those additional venues is at the discretion and approval of the Commissioner.

Providers will also need to extend their CQC licence under the temporary provision to register the additional venue.

Further guidance for local commissioners can be found in our letter.

Operating model: the most scalable model would be to hold temporary vaccination clinics at the chosen location, similar to the vaccination in care homes model, which deploys a small roving vaccination team to visit the location to administer the

vaccine. These clinics could be on a one-off or rolling basis (e.g. weekly) depending on demand.

Further information on the care homes roving model, including the suggested make-up of the roving team, and guidance on cold chain management, can be found in Appendix D of this SOP and should be followed.

Call/recall and booking: PCN Groupings should follow existing call/recall processes for registered patients according to JCVI eligibility for vaccination, highlighting the opportunity to book appointments at the temporary vaccination clinic. Faith and community leaders may be able to support in raising awareness of the opportunity to be vaccinated at the temporary clinic among local communities.

Vaccine: The Oxford/AstraZeneca (AZ) vaccine is recommended for temporary vaccination clinics and our position statement on the vaccination of care home residents using AZ provides guidance on the safe and aseptic movement of this vaccine and should be followed.

Vaccine allocations to PCN-led sites are currently based on eligible JCVI cohorts and population size. Existing PCN allocations should therefore be used for additional temporary vaccination clinics.

In addition, community pharmacy providers should utilise their existing allocations for temporary vaccination clinics.

If the LVS provider considers they need more vaccine to deliver temporary vaccination clinics, they should notify their commissioner as soon as possible via the usual channels.

Vaccine and related consumables should not be stored at the venue overnight.

Equipment, consumables and PPE: Ensure vaccinator teams have all necessary roving Supply Inventory List (SIL) items. Most PCN-led sites have received one roving SIL per site, which means that the roving team can only visit one care home, housebound patient or additional location at a time. The additional location vaccination clinic could not therefore be held concurrently with other roving visits unless additional SIL items are available. Where the temporary vaccination clinic will be held for a longer period (i.e. once a week for 5 months), the LVS provider could request an additional roving SIL from NHS England. If equipment/chairs/tables/screens are needed, commissioners should seek to provide this through mutual aid.

Technology: This model would require use of the two laptops and barcode scanners originally supplied to PCN and Community Pharmacy led sites to support roving vaccinations.

Consent: Follow guidance set out in section 4.5 and Appendix D of this SOP; additional preparation may be needed to support those who live alone or those who lack mental capacity, before the time of the scheduled clinic.

Clinical review: Consider completing an initial clinical review to assess the patients suitability for vaccination prior to the clinic if possible; this should be repeated prior to vaccination as set out in section 4.6 of this SOP.

Post vaccine observation and adverse reactions: Further information on post vaccine observation and record keeping can be found in section 4.7 and 4.8 of this SOP. The roving vaccination team should record in Pinnacle/Outcomes for Health during the temporary clinic as if they were vaccinating at their designated site. 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.

Patients and/or their carers should know who to contact if they are concerned about any effects that may be experienced after the vaccination. In most cases, this is the patient's own GP.

Site configuration: LVS providers should discuss site configuration with the manager of the venue in advance of the scheduled temporary vaccination clinic. There should be an appropriate area for vaccine preparation and delivery maintaining patient confidentiality, privacy and social distancing, applying all guidance set out in section 2.3 (Site preparation) of this SOP. This should also include adherence to IPC guidance (section 2.6).

Temporary vaccination clinics should ensure the venue set-up includes having a sensible place for the cool box (minimising risk to the cold chain), a sterile area for dilution / reconstitution of vials, an area for administering vaccines, and an area and system for post observation of residents.

Commissioners should undertake a visit to ensure the venue meets minimum requirements and a checklist is provided as part of our guidance to local commissioners provided in the letter referred to above. The arrangements set out in the letter of 7 January would also apply. These include:

- Practices/PCN groupings must continue to meet all of the requirements within the COVID-19 Vaccination Programme 2020/21 Enhanced Service Specification and there will be no change to current PCN grouping set-up and supply arrangements. Community Pharmacy Contractors must continue to meet all the requirements of the Local Enhanced Service in place at that time, and will require authorisation from their Commissioner to provide vaccination at any venue other than the Designated Site listed in the LES document.

- All vaccines and vaccine-related consumables will continue to be delivered to PCN and Community Pharmacy designated sites only and will not be delivered to alternative premises.
- PCN and pharmacy contractors will need to transport the AZ vaccine, consumables and equipment from the designated site to the temporary vaccination clinic.
- Any vaccinations administered at the temporary vaccination clinic should be recorded via Pinnacle/Outcomes for Health against the existing lead practice ODS code of the PCN grouping e.g. new accounts will not be set up. Pharmacies will record all vaccinations against the ODS code of the designated site.
- LVS providers will need to ensure that the temporary vaccination clinic venue supports compliance with any requirements in relation to the storage, preparation, administration and disposal of the vaccine and associated consumables as well as relevant guidance e.g. in relation to social distancing or security.
- LVS providers should ensure that they have a robust system in place for maintaining the cold chain, recording any movement of the AZ vaccine from designated sites and vaccine wastage.

Appendix I: Operating model for drive-through clinics

This section should be read in conjunction with all other content in this SOP, including Section 4, which includes the core operating model for LVS deployment in community settings.

To help improve patient access, in particular to maximise take up of the vaccine in communities or among groups with relatively low coverage, PCN groupings and Community Pharmacy Contractors can administer vaccines via a drive-through clinic.

Drive-through clinics can be operated at the designated sites or from appropriate locations other than those which have been specifically designated for COVID-19 vaccination. Our letter of 7 January outlining the additional operational flexibilities offered by the Oxford/AstraZeneca vaccine provides the framework for this to take place. Drive-through clinics at an alternative location will not be considered as new designated sites.

Drive-through clinics, where appropriate to the needs of the local population, should be seen as an additional or expanded offer rather than a replacement for vaccination provision currently in operation. Local commissioners are encouraged to work with existing contractors to establish drive-through clinics where this will help to improve uptake in areas with low coverage.

Whilst there is no requirement for existing Providers to deploy drive-through clinics, we would expect all Regional teams to be working with their Local Authority (LA) and Local Resilience Forum (LRF) partners to analyse their current and forecasted coverage profile from a geographic and population specific perspective to determine if such provision will better meet the needs of the populations they serve.

Particular considerations should include travel times to vaccination locations, ease of access for historically underserved communities and targeting of areas with greatest health inequalities. Regions should access the COVID-19 Vaccine Equalities Tool to support decision making in this regard.

Drive-through clinics at the designated site

PCN groupings and Community Pharmacy Contractors may deliver drive-through clinics at the designated site (i.e. the site car park) under the terms of existing contracts, the Enhanced Service Specification and Local Enhanced Service

respectively, if agreed as part of the original clinical assurance of the site. If this was not agreed as part of the original clinical assurance process, providers should inform the commissioner in writing of their intention to use the designated site in this way.

Drive-through clinics at an alternative location

Where the clinic is proposed at an alternative location to the designated site, for PCN groupings, the commissioner will need to approve and confirm the arrangements in writing. This should include clarifying who the PCN grouping can vaccinate at drive-through clinics. For example, the commissioner should clarify whether the PCN grouping could vaccinate an eligible patient registered with another PCN grouping at the clinic if they presented.

Community Pharmacy contractors must be approved by NHSEI to provide vaccinations at drive-through clinics at venues other than the Designated Site with their LES agreement. NHSEI will amend the LES document to ensure that the nature of those additional venues is at the discretion and approval of the Commissioner.

PCN providers will also need to extend their Care Quality Commission (CQC) licence under the temporary provision to register the additional location. Community pharmacy contractors must ensure they can comply with General Pharmaceutical Council (GPhC) standards and should refer to the GPhC guidance for providing COVID-19 vaccination.

Operating model: Drive-through clinics can be deployed at the designated site should estate infrastructure permit and the resulting impact on existing service provision be deemed appropriate by the local commissioner. Alternatively, drive-through clinics can be deployed at alternative appropriate locations within the surrounding area where there is an identified need. In both instances Providers should adhere to the guidance set out in this SOP.

Insurance (including public liability): where the drive-through clinic is to be held at the designated site, providers will need to inform their insurer that they are changing the nature of the service being provided with a request to extend the existing insurance policy. We anticipate that for the most part providers may already be covered for this extended activity under their existing insurance policy.

Where the drive-through clinic is to be held at an alternative location to the designated site, providers will need to inform their insurer of the location at which they intend to hold the drive-through clinic, and request an extension of their existing insurance policy. Individual insurers will need to determine whether this extended activity is already covered by the existing insurance policy, or whether additional insurance will be required.

State indemnity in relation to clinical negligence applies to vaccines given as part of the national COVID-19 vaccine deployment programme regardless of location.

Vaccine: The only COVID-19 vaccine currently appropriate for use in the drive-through clinics is Oxford / AstraZeneca due to the delicate nature and transporting restrictions with the mRNA vaccines (Pfizer/BioNTech and Moderna). This will be reviewed as and when other vaccine candidates become available. Note: our position statements on using the Oxford/AstraZeneca vaccine for the vaccination of care home residents and to vaccinate housebound patients provides guidance on the safe and aseptic movement of this vaccine and should be followed.

Vaccine allocations to PCN-led sites are currently based on eligible JCVI cohorts and population size. Existing PCN allocations should therefore be used for additional drive-through clinics.

Community pharmacy providers should utilise their existing allocations for drive-through clinics.

If the LVS Provider considers they need more vaccine to deliver drive-through clinics, they should notify their commissioner as soon as possible via the usual channels.

Call/recall and booking: PCN Groupings should follow existing call/recall processes for registered patients according to JCVI eligibility for vaccination, highlighting the opportunity to book appointments at the drive-through clinic.

Individuals booking vaccination or responding to an invitation can be offered the choice of receiving vaccination via drive-through or at the Provider's designated site (should that location be different). Providers managing their own booking systems should ensure their systems can cater for this. Booking systems should make clear that drive-through vaccination cannot be utilised by those aged 16 and 17 (see under heading *Cohort*).

Community pharmacy contractors should work with their regional team in relation to appointment bookings for the drive-through clinic, whether via the National Booking System (NBS) or a local booking solution.

When booking patient appointments for the first dose, appointments should be made for the second dose simultaneously, to take place 11 weeks (or 77-84 days) later. Please refer to our FAQs on second doses for more information.

Cohort: Drive-through vaccination should be accessible to eligible priority cohorts as defined by JCVI[1,2] and within Public Health England's Green Book Chapter 14a.[3]

Vaccination of individuals aged 16 and 17 should not be available via drive-through clinics as currently the Pfizer/BioNTech vaccine is the only licenced vaccine for use in those aged 16 and 17. Should anyone aged 16 or 17 present to a drive-through clinic for vaccination, they should be referred to an alternative setting where they can access appropriate vaccination. Any use of alternative vaccines for these individuals would be outside of the licence and should be managed by PCN LVSs at their designated site or by Hospital Hubs under a Patient Specific Direction (PSD), by a prescriber.

Equipment, consumables and Personal Protective Equipment (PPE): Providers must ensure vaccination teams have all necessary items from the Supply Inventory List (SIL – equipment, consumables and PPE). The items required will depend on whether the drive-through clinic will be held at the designated site or at an alternative location, and if the latter, then some of the additional items provided with the roving SIL will be required. The Provider must ensure that Basic Life Saving Equipment and supplies for the management of potential adverse drug reactions (including anaphylaxis) are present during all hours of operation.

Note: Most PCN-led sites have received one roving SIL per site, which means that the roving team can only visit one care home, housebound patient or run a clinic in an additional location at a time. The drive-through if at an alternative location could not therefore be held concurrently with other roving visits unless additional SIL

[1] https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020
[2] https://www.gov.uk/government/publications/priority-groups-for-phase-2-of-the-coronavirus-covid-19-vaccination-programme-advice-from-the-jcvi/jcvi-interim-statement-on-phase-2-of-the-covid-19-vaccination-programme
[3] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/961287/Greenbook_chapter_14a_v7_12Feb2021.pdf

items are available. Where the drive-through clinic will be held for a longer period (i.e. once a week for a number of months), the LVS provider could request an additional roving SIL from NHS England.

Any additional materials required by Providers that may be necessary to operationalise drive-through clinics e.g. canopies, drive-through clinic-specific PPE (e.g. hi-vis jackets) etc. will not be supplied by the national team and should be sourced locally, for example by commissioners seeking mutual aid.

Technology: Screening and vaccination event data capture must be done electronically using Outcomes4Health (Pinnacle) Point of Care System; this necessitates the requirement for appropriate mobile devices (e.g. tablets) with 4G connectivity. The accessibility of 4G connectivity should be a key consideration for selection of the drive-through clinic location. The drive-through model would require use of the two mobile devices (i.e. laptops or tablets) and barcode scanners originally supplied to PCN and Community Pharmacy-led sites.

Consent: Follow guidance set out in section 4.5 and Appendix D of this SOP; additional preparation may be needed to support those who lack capacity to provide informed consent, before the time of the scheduled clinic.

Clinical review: Providers should consider completing an initial clinical review to assess the individual's suitability for vaccination prior to the clinic if possible; this should be repeated prior to vaccination as set out in section 4.6 of this SOP. Tasks completed in advance will need to be checked by a Registered Healthcare Professional before administration of the vaccine.

Post vaccine observation and adverse reactions: There is no period of post-vaccination observation mandated for the Oxford/AstraZeneca vaccine unless this is indicated after clinical assessment or where the patient has experienced an adverse reaction to a previous vaccination dose. Therefore, where the vehicle driver has not been vaccinated, there is no requirement for the vehicle or its occupants to remain in-situ post vaccination. There should be the clear provision of information and appropriate signposting for individuals on how to seek support should it be required.

Where the driver of the vehicle has been vaccinated, the vehicle should remain stationary for a period of 15 minutes post the driver's vaccination because of the risk of syncope (fainting). The Provider should ensure that appropriate provisions

are in place for the vehicle to remain stationary for this period without unduly interrupting the flow of subsequent vehicles. One solution would be to have one or more parking areas where patients will receive their vaccination and that are separate from and will not block entrance and exit points. Stewards will be needed to direct drivers to available spaces in the parking area(s) and then direct them out again once 15 minutes have elapsed (if the driver is also the patient).

An on-site ambulance is not a pre-requisite for a drive-through clinic but the Provider should ensure the appropriate provision of facilities in the event of an adverse reaction e.g. a location where an individual can receive appropriate clinical treatment. There should be a clear process for how individuals are taken to this location should it be required.

For Providers not electing to have paramedic or ambulance provision on site it is recommended that a dialogue takes place with the local ambulance provider during the planning phase to ensure they understand the facilities at the drive-through location and can allocate the right priority and support at times of high demand.

Further information on post vaccine observation and record keeping can be found in section 4.7 and 4.8 of this SOP. The team should record in Pinnacle/Outcomes for Health during the drive-through clinic as if they were vaccinating at their designated site. Patients should be given a post vaccination record card with details of their vaccination and confirming the second dose appointment, which should have been made at the point of booking the first dose appointment.

Patients and/or their carers should know who to contact if they are concerned about any effects that may be experienced after the vaccination. In most cases, this is the patient's own GP.

Infection Prevention and Control: Consideration must be given to both infection prevention and control (IPC) and the safe and secure handling and preparation of the vaccine within drive-through clinics to ensure that the relevant legislation and guidance is adhered to. Providers should refer to the following information:

- This letter from Keith Ridge, NHS England and NHS Improvement Chief Pharmaceutical Officer
- Patient Group Direction for Oxford / AstraZeneca here
- National Protocol for administration of Oxford / AstraZeneca here
- Guidance on IPC here.

Providers must identify specific and appropriate IPC lead/Director of IPC (DIPC) sign off mechanisms with particular attention to waste management, water quality, cleaning requirements and the area for vaccine preparation. This should include compliance with MHRA licensing conditions including following Specialist Pharmacy Service (SPS) protocols.

Estates: A range of potential locations may prove suitable for drive-through vaccination from GP practice or Vaccination Centre car parks to other hardstanding areas with good local road links. If selecting a location where vaccination services are already delivered, Providers should ensure the drive-through clinics do not negatively impact on the provision of other healthcare services delivered at that site. In all incidences, impact of traffic flows on the surrounding traffic network should be considered and appropriately planned for. As a courtesy, the local police should also be informed of the drive-through clinic location and activity.

Locations selected should be accessible to emergency services vehicles in the event of an untoward incident. This includes there being sufficient space between patients' cars to allow the emergency services to easily access a patient in their car if necessary.

Regions and Providers should continue to liaise with local authorities and Local Resilience Forums (LRFs) as drive-through clinics are mobilised. The LRFs will also have a key role in determining location suitability.

Workforce and training: The Provider must ensure that appropriate policies, procedures and training are in place to manage:

- clinical governance,
- clinical supervision,
- clinical escalation,
- management, storage and use of vaccines,
- maintenance of Aseptic Non-Touch Technique (ANTT),
- clinical and non-clinical waste management,
- vaccine handing including preparation, draw-up and transportation,
- adverse drug reactions (this should include advice being provided to vehicle occupants on how and when to call for assistance plus mechanisms for site staff to alert one another), and,
- emergency management.

This is not intended to be a comprehensive list and providers should consider other workforce and training that may be required to deliver the services.

These policies, procedures and training must be in place prior to a drive-through clinic going live and should be tested, with compliance demonstrated in the run up to clinic launch and be reviewed periodically thereafter.

A number of key workforce requirements concerning COVID-19 vaccination operating under the National Protocol have been developed and are found within Appendix A. The Provider must ensure that these requirements are met.

The key functions for drive-through vaccination clinics include:

- Site stewarding.
- Site security.
- Site registration and “front of house”.
- Safe storage and management of vaccines.
- Vaccine preparation.
- Waste management.
- Clinical supervision.
- Vaccine administration.
- Vaccine data recording.
- IPC lead.
- Overall site management.

Providers must ensure that the staff are of sufficient seniority, have received the appropriate training, have the necessary skills and knowledge and are present in sufficient capacity to discharge these functions. Whilst it is not a requirement to have Paramedic trained staff on site, Providers may wish to consider the demonstrable benefit of having staff on site whom are experienced in pre-hospital emergencies in difficult conditions.

Providers must ensure the appropriate level of clinical supervision and seniority is physically present on-site during hours of operation, in line with national guidelines and legislation.

Site configuration: LVS providers should discuss site configuration with the manager of the location (if applicable) in advance of the scheduled drive-through clinic.

There should be an appropriate area for vaccine preparation and all applicable guidance set out in section 2.3 (Site preparation) of this SOP should be followed. This should also include adherence to IPC guidance (section 2.6).

Providers should ensure that drive-through clinic sites are set-up to include having a sensible place for the cool box (minimising risk to the cold chain), a sterile area for dilution / reconstitution of vials, an area for administering vaccines that offers protection from the elements, and an appropriate area and system for management of adverse vaccination reactions amongst other appropriate considerations having regard to the proposed site location.

Vaccines must be transported only in approved and validated cool boxes, and the temperature of the cool box and contents must be monitored and reviewed before use in order to maintain cold chain requirements. Means of detecting when a temperature excursion has occurred are required and that any 'out of specification' recordings are addressed promptly and appropriately, and that a full audit trail is maintained.

For more information on cold chain management, preparation, training, validation and a visual end-to-end journey of the cold chain, please refer to Appendix D of this SOP on the 'Operating model for providing local vaccination services in care homes'.

Commissioners should undertake a visit to ensure the location meets the guidance in this SOP, in the following two scenarios:

- Where the drive-through is being delivered from an alternative location to the designated site;
- Where the drive-through is being delivered from the designated site, but this was not agreed as part of clinical assurance of the site originally.

The arrangements set out in the letter of 7 January would also apply. These include:

- Practices/PCN groupings must continue to meet all of the requirements within the COVID-19 Vaccination Programme 2020/21 Enhanced Service Specification and there will be no change to current PCN grouping set-up and supply arrangements. Community Pharmacy Contractors must continue to meet all the requirements of the Local Enhanced Service in place at that

time, and will require authorisation from their Commissioner to provide drive-through vaccination clinics at any venue other than the Designated Site listed in the LES agreement.

- All vaccines and vaccine-related consumables will continue to be delivered to PCN and Community Pharmacy designated sites only and will not be delivered to alternative premises.
- PCN and pharmacy contractors will need to transport the Oxford/AstraZeneca vaccine, consumables and equipment from the designated site to the drive-through clinic site.
- Any vaccinations administered at the drive-through clinic should be recorded via Pinnacle/Outcomes for Health against the existing lead practice ODS code of the PCN grouping e.g. new accounts will not be set up. Pharmacies will record all vaccinations against the ODS code of the designated site.
- LVS providers will need to ensure that the drive-through clinic site supports compliance with any requirements in relation to the storage, preparation, administration and disposal of the vaccine and associated consumables as well as relevant guidance e.g. in relation to social distancing or security.
- LVS providers should ensure that they have a robust system in place for maintaining the cold chain, recording any movement of the Oxford/AstraZeneca vaccine from designated sites and vaccine wastage.