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Standard Operating Procedure: Roving and mobile models

Updates made to this document are highlighted in yellow

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 is accurate.

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1. Scope and purpose

This standard operating procedure (SOP) describes how to operate roving and mobile vaccination models. These models enable the administration of COVID-19 vaccines at identified locations outside of vaccination 'base' sites: vaccination centres; hospital hubs; designated PCN-led sites; and designated community pharmacy-led sites. They include care homes, vaccination for housebound patients, other residential settings or settings of multiple occupancy, temporary vaccination clinics (e.g. pop-ups), vaccination buses and drive-through clinics.

The aim of roving and mobile models is to improve access and maximise vaccine uptake in communities or among groups where uptake is low.

1.1 General guidance and advice

This SOP must be read in conjunction with:

For Phase 3: <u>Joint Committee on Vaccination and Immunisation (JCVI) regarding a</u>

<u>COVID-19 booster vaccine programme for winter 2021 to 2022</u> (published 14 September 2021).

For the evergreen offer:

- JCVI guidance defining eligible cohorts from <u>December 2020</u> and <u>April 2021</u>.
- <u>The Green Book</u>, particularly <u>chapter 14a</u> and <u>chapter 2</u>, and the UK Health Security Agency's <u>COVID-19 vaccination programme webpage</u>.
- Vaccine-specific guidance should be followed. COVID-19 vaccines have different characteristics with specific handling requirements which are a condition of temporary authorisation under Regulation 174 of the Human Medicines Regulations 2012. Vaccine-specific SOPs are on the Specialist Pharmacy Service website.
- <u>Maximising vaccine uptake in underserved communities: a framework for systems, sites and local authorities leading vaccination delivery provides a problem-solving framework, best practice and practical guidance for implementing a range of interventions to ensure equitable access.</u>
- Legal mechanisms for administration of COVID-19 vaccine.
- JCVI guidance on vaccinating children aged 12 to 15 years (3 September).

In addition, the following documents apply:

- Vaccination Centres (VC): <u>Vaccination Centre Operating Framework</u> and POD definition document.
- Local Vaccination Services (LVS): SOP <u>COVID-19 local vaccination services</u> deployment in community settings.

- COVID-19 Vaccination Programme <u>Service Specifications: Vaccination Centres</u>
 (<u>including Hospital Hubs</u>); <u>Enhanced Service Specification: <u>COVID-19 vaccination</u>
 <u>programme for general practice</u> (GP-led vaccinations only); <u>Enhanced Service</u>
 <u>Vaccination Collaboration Agreement;</u> <u>Local Enhanced Service Agreement: <u>COVID-19 vaccination programme for community pharmacy</u> (community pharmacy-led vaccinations only).
 </u></u>
- Resources for communicating with the public are available to sites, including in accessible formats. Further resources are on the <u>FutureNHS Communications and</u> <u>Engagement pages</u>.
- Additional <u>training materials for COVID 19 vaccinators and volunteers</u> provide tips on communicating with people with a learning disability and autistic people and reasonable adjustments that should be considered.
- NHS England's guidance is on our website and on the FutureNHS workspace.¹

2. Preparing for roving and mobile vaccination

Vaccines, vaccine-related consumables and equipment will continue to be delivered to the respective vaccination base sites (e.g. for LVS sites the designated site) and need to be transported from there to the mobile vaccination site or end-user location. Section 4.1 outlines the requirements for moving and transporting the different vaccines.

Equipment (including IT/hardware) to support the vaccination process should be ordered by the designated vaccination base site, further guidance outlined in section 4.2.

Sections 3.1 to 3.3 and appendices A-C outline the different operating models in more detail.

2.1 Governance

Regions, ICSs and providers will work together to assure roving and mobile vaccination services, in line with the requirements in this SOP.

Regions and ICSs must have a roving and mobile vaccination delivery strategy, including target cohorts, cohort vaccination penetration objectives, and a clear assurance process. An Equality and Health Inequalities Impact Assessment (EHIA) should be completed to assess the strategy.

¹ New users can join FutureNHS by emailing P.C. N-manager@future.nhs.uk from an NHS email address (or similar work email address of eligible users). Guidance, support and resources to help teams to ensure equality of access to the vaccine are available on the COVID-19 Vaccine Equalities Connect and Exchange Hub on Future NHS.

Interventions should be designed and adapted locally in partnership with local authorities, community networks, faith groups, community leaders and other partners. Operational delivery requirements should be confirmed during the set-up phase to maximise vaccinations, minimise vaccine waste and increase uptake where this is low (<75 per cent of the eligible cohort), as per JCVI guidance.

Providers must have a signed-off assurance process document prior to administering vaccinations, and work through their existing contractual arrangements where needed.

For VCs and HHs, the assurance process should be endorsed by the Regional Senior Responsible Officer (SRO)/Regional Director of Commissioning (RDC) after a recommendation from the Vaccination Lead within the Integrated Care System (ICS). Clinical assurance of the service should be led by a named responsible pharmacist. The regional Chief Pharmacist should assure themselves that the appropriate clinical checklists on Foundry have been completed, that the <u>Specialist Pharmacy Service (SPS)</u> guidance has been followed, and that the <u>Standard Operating Procedures on handling multiple</u> vaccines and cold chain management have been complied with.

For LVSs, section 4.6 sets out further contractual and operational requirements.

Once assured, calendars can be opened on the National Booking Service (NBS), where applicable. Details are in the <u>NBS SOP</u>. Call/recall and booking arrangements should follow the normal process in accordance with JCVI eligibility criteria for vaccination.

All designated vaccination base sites should consider:

- Capacity planning: how roving and mobile site teams will contribute to vaccinating eligible cohorts in their local population and identify targets for the outreach programme.
- Inequalities in vaccination uptake: as a minimum, regions, ICSs and vaccination base sites should have used the inequalities tool/s i.e. SHAPE/ geospatial analysis and consulted with local communities to determine the site location. Equality and Health Inequalities Impact Assessments (EHIAs) should be conducted both regionally and at the provider level.
- The workforce plan needed, expected vaccination throughput and respective requirements to deliver vaccinations (e.g. additional skill sets such as languages and knowledge of local communities).
- Site configurations for different roving and mobile models (see section 3.1 to 3.3 and appendices A-C). Ensuring a robust system for maintaining the cold chain and recording any movement of vaccines from base sites and vaccine wastage.
- Planning service delivery in line with stock forecasting and ordering arrangements including:
 - planning mobile clinics or roving team schedules according to expected vaccine supply

- co-ordinating the trained staff required
- ordering required vaccine and consumables supply within required timeframes
- monitoring vaccination uptake within their local communities, in particular within ethnic minority, marginalised, and deprived communities.

Table 1: an overview of mobile and roving models

Delivery model	Location	Eligible and target cohorts
Roving model Delivery of vaccine to end-user location through roving teams. Roving models to distinguish single and multiple movements of vaccine during one shift following supply from vaccination base site (e.g. the designated PCN/ CP-led sites).	individuals in both NHS and	Eligible individuals living within residential sites, including care and nursing homes and non-older adult care homes including care homes for people with a learning disability etc. Health and social care staff working within residential sites referred to above. Settings of multiple occupancy including, but not limited to, secure mental health and mental health inpatient units. Individuals in settings of single occupancy who are housebound ² . People who may experience barriers to accessing health services, including, but not limited
Mobile model Targeted vaccinations at locations temporarily installed outside of base sites e.g. vaccination 'buses' or vaccination 'satellite' sites For LVS providers, this model is commonly referred to as temporary vaccination clinics (or 'pop-ups') in community settings.	NHS and non- NHS sites	to, people experiencing homelessness and traveller communities. Communities identified with low vaccination uptake (<75 per cent of the eligible cohort). Cohorts and groups at higher risk of serious disease and hospitalisation, including groups associated with an increased risk and occupational groups at higher risk of exposure as defined in JCVI guidance.

² The patient is classed as housebound due to being unable to leave their home at all or requires significant assistance to leave the house due to illness, frailty, surgery, mental ill health or nearing end of life.

Single movement of vaccine during shift from base site to temporary vaccination clinic.		
Drive-throughs	NHS and non- NHS sites	Eligible cohorts as defined in JCVI guidance.
Drive-through clinics can be operated either at the respective base site or from appropriate locations other than those which have been specifically designated for COVID-19 vaccination.		

2.2 Security

Providers should take proactive steps to develop and maintain a strong security culture within their vaccination sites and this includes roving and mobile sites.

To achieve this, providers should take steps to make sure that staff and volunteers have a consistent approach to site security:

- there should be a clear and regularly revised understanding of the main risks
- staff and volunteers should have a clear understanding of what is required of them.

2.21 Security plan

For roving and mobile models, providers should review their security plan, including arrangements to manage the following risk areas:

- site inductions making sure that all personnel involved in the site are made aware
 of the security arrangements and responsibilities
- awareness making time available for site staff and volunteers to undertake relevant security training, including <u>Action Counter Terrorism (ACT)</u> e-learning
- briefings involving all site staff and volunteers in regular briefings about the operation of the site and the associated security arrangements
- reporting creating a culture where site staff and volunteers can easily report any security concerns and making sure that learning and feedback is shared from these.

Providers of roving and mobile units should consider the nature of the site and work with the local police and, if appropriate, local resilience forum (LRF) partners to inform security-focused SOPs required to ensure the safe operation of the site. Providers should complete a site security risk assessment for the roving and mobile site as part of their preparation for readiness. Site leads are required to follow the guidance on the security of premises and the personal safety of staff available here. Guidance on managing challenging behaviour is available here.

The site-specific risk assessment should include as a minimum:

- site security roles and responsibilities, including engagement with local police partners
- site access and external controls. Depending on the nature of the site, this might include issues such as traffic and queue management
- vaccine storage, movement and access to vaccine stores
- emergency responses to a range of possible scenarios, including procedures for site
 evacuation and to instigate a lockdown of the site
- waste management arrangements (for COVID-19 vaccine products)
- information security
- out-of-hours security arrangements (especially where vaccine products will be stored on-site overnight).

Roving and mobile model access: Make sure there are clear protocols in place to control access, both for staff and patients attending vaccinations. There is a risk that protestors may try and pose as either patients or staff.

Staff security: Consider protocols to minimise the risks to staff when on location and conducting vaccination operations.

Incident protocols: Ensure there are clear protocols in place to respond to any security incident. This should include clear roles and responsibilities, including how sites would be locked down in the event of a security incident.

Security staffing: Determine requirements for on-site security presence, and make sure that any contracted security staff are SIA accredited. Review levels of security staffing to determine whether it is commensurate with the risk presented to the roving and mobile programme.

3. Roving and mobile operating models

3.1 Roving models

Roving models deploy small vaccination teams to one or multiple sites, including:

- care homes e.g. for older adults or non-adults, adult care homes including care homes for people with learning disabilities or Serious Mental Illness (SMI)
- secure mental health facilities and mental health inpatients
- other residential settings or settings of multiple occupancy e.g. hostels/hotels for people experiencing homelessness
- in the homes of people who are housebound and patients with additional access needs.

The type of vaccine used depends on whether the model is to 'multiple sites' or 'one site' during one shift, as set out in section 4.1, Table 2.

PCN groupings and CP contractors can administer COVID-19 vaccines from locations other than their designated site where the local commissioner approves this and MHRA guidelines on the movement of vaccine are followed. A checklist for LVS sites is included as Appendix D. LVS providers should work with their CCG, ICS, local authorities and other community partners to establish the most effective ways to reach different groups and determine the most appropriate vaccination delivery model. Contractual and other requirements are set out in section 4.6.

Site configurations: key considerations for roving teams include:

- venue set-up with appropriate location for the cool box, a sterile area for vaccine preparation (dilution / reconstitution of vials), an area for administering vaccines while maintaining patient confidentiality and privacy, and an area and system for post-observation of patients
- transport requirements and the maximum time the vaccine can be safely stored in the cool box, as set out in section 4.1.

Key operational considerations include:

- Workforce: the composition of the roving vaccination team should reflect the skill-mix required in the <u>National Protocols</u>, <u>PGDs and local PSD</u>, the number and age of patients to be vaccinated, and any specific requirements of patients or the roving site. An example visit schedule and workforce set-up for care homes are in Appendix A.
- Consideration should be given to reflect local/target population diversity in the workforce and/or volunteers supporting roving and mobile vaccination delivery.

- The consent discussion (see section 5.1). Additional preparation may be needed to support those who live alone, lack mental capacity, young people and children.
 Additional considerations for people with Serious Mental Illness (SMI), dementia, a learning disability or autistic people can be found here.
- Clinical review: an initial clinical review to assess patients' suitability for vaccination prior to the roving visit should be considered. A clinical assessment prior to vaccination must be carried out (see section 5.2).
- Post-vaccine observation periods should follow normal arrangements for observation after vaccination and pharmacovigilance, as set out in the <u>Green Book</u>.

3.2 Mobile models

Mobile models include the temporary installation of stationary vaccination clinics at locations other than the established vaccination base site (e.g. the designated PCN/CP-led site).

A mobile treatment centre or a vaccination bus are considered static/stationary if they remain at the identified location during a shift. For mobile vaccination clinics such as vaccination buses, an assurance checklist developed for the St John Ambulance mobile treatment centres pilot is in Appendix B.

Mobile clinics can be on a one-off or rolling basis (e.g. weekly) depending on demand and outreach strategic objectives. They should meet community access needs, including flexibility in operating hours as well as delivery model.

The vaccination base site will provide appropriate governance and be responsible for the deployment and logistics. For VCs and HHs, the assurance processes will be set out by clinical leads and regional leads.

Considerations for PCN groupings and Community Pharmacy Contractors

PCN groupings and CP 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 <u>our guidance and subject to local commissioner agreement.</u>
Sites must comply with the latest rules on the movement of vaccines; see section 4.1.
Section 3.4 sets out further requirements for the vaccination of children and young adults through mobile and roving models.

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. Commissioners should clarify whether the PCN grouping could vaccinate an eligible patient registered with another PCN grouping at the clinic. PCN groupings that have been approved to vaccinate cohorts 10-13 are able to vaccinate any eligible patient in those cohorts including those not registered with a practice in the PCN grouping.

Site configuration:

For PCN and CP-led vaccination sites, Appendix D sets out further guidance, including a checklist for the venue with minimum requirements.

The venue should have an appropriate area for i) arrival and check-in, ii) clinical assessment, and iii) vaccine administration that allows for:

- vaccine preparation i.e. a sterile area for dilution / reconstitution of vials;
- maintaining patient confidentiality, privacy, and social distancing;
- an area and system for post-observation of patients.

A clinical area is required to draw up the vaccine, and the registered healthcare practitioner operating under the respective National Protocol, PGD or PSD will supply the clinicians assessing and administering the vaccination. The suitability of a location to maintain infection prevention and control as well as social distancing requirements needs to be considered. The appointment is expected to take no longer than 10 minutes. Depending on vaccine type, driving status and outcome of the clinical assessment, a 15 min post-vaccination period may be required.

Mobile vaccination vehicles such as buses must not be left on site overnight unattended; the vehicle will be taken back for cleaning / servicing at the end of each operational clinic day.

For LVS providers, local commissioners should visit the venue to ensure it meets minimum requirements and should discuss site configuration with the venue manager in advance.

Key considerations:

- Providers must ensure compliance with any requirements for the storage, preparation, administration and disposal of the vaccine and associated consumables.
- Providers must have a process in place to manage patient flow, follow Infection Prevention and Control (IPC) requirements, and social distancing, and ensure eligibility of service users in line with JCVI guidance.
- Contractual and other requirements are set out in section 4.6.

3.3 Drive-through vaccination clinics

Drive-through clinics are an additional or expanded offer. Occasional drive-through clinics at an alternative location are not considered as new sites. Drive-through clinics can be operated either at the respective vaccination base site (e.g. the designated PCN/CP-led site) or from appropriate locations other than those which have been specifically established for COVID-19 vaccination. If drive-throughs at an alternate site are a regular feature, these should go through programme assurance.

Local commissioners are encouraged to work with existing contractors to establish drivethrough clinics where this will help access to vaccination services and increase capacity.

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.

Site configuration:

- providers should ensure the drive-through clinics do not negatively impact on the provision of other healthcare services delivered at that site.
- The local police should be informed of the drive-through clinic location and activity.
 Locations selected should be accessible to emergency services vehicles in the event of an incident.
- The provider should ensure that appropriate provisions are in place for vehicles to remain stationary for the 15-min post-vaccination observation period required after vaccination with Pfizer (Comirnaty ®) or Moderna without interrupting the flow of subsequent vehicles. The vehicle must remain *in-situ* post-vaccination for the recommended time period. One solution is the provision of one or more parking areas where patients will receive their vaccination and that are separate from and will not block entrance and exit points.

Commissioners should visit the location to ensure it meets the requirements in this SOP, in the following two scenarios:

- 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.
- Where the drive-through is being delivered from an alternative location to the designated site.

Drive-through clinics at the designated site

Service providers may deliver drive-through clinics at the base site i.e. the site car park:

- For PCN groupings and CP contractors, drive-through clinics at the designated site
 can be delivered 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 and seek approval from their local commissioner.

 For VCs and HHs, drive-through clinics can be delivered under the terms of the existing contracts. Appendix D includes an example configuration and key operating processes for a drive-through at VCs.

<u>Drive-through clinics at an alternative location</u>

Where the clinic is proposed at an alternative location there are additional considerations to ensure good governance and operational policy:

- For VCs and HHs, the trust chief pharmacist will need to approve and confirm the arrangements in writing.
- CP contractors must be approved by NHS England and NHS Improvement to provide vaccinations at drive-through clinics at venues other than the designated site.
- PCN Groupings must also be approved by NHS England and NHS Improvement to provide vaccinations at drive-through clinics at venues other than their designated site.
- LVS providers must extend their CQC licence under the temporary provision to register the additional venue.

Other key considerations

- If the drive-through clinic is at the base site, providers must inform their insurer that they are changing the nature of the service being provided and request to extend the existing insurance policy.
- If the drive-through clinic is at an alternative location, 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.
- Workforce: the provider must ensure that appropriate policies, procedures and training are in place prior to a drive-through clinic going live, with compliance demonstrated in the run up to the clinic launch, and with follow-up reviews.
- The key processes 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
- o IPC lead
- Overall site management.

3.4 Vaccination of children and young people

Pfizer/BioNTech BNT162b2 (Comirnaty®) is the recommended vaccine for vaccinating patients under 18 years. The PGD and National Protocol have been updated for this vaccine.

The guidance outlined in section 3.4 applies to the vaccination of children aged 12 to 15 years who are clinically vulnerable or household contacts. While this section does not cover guidance for the universal vaccination of all children aged 12 to 15 years into all delivery models, the principles and requirements equally apply. The universal vaccination of all young people aged 12-15 (who are not already covered by JCVI advice) is being provided predominantly by the Schools Aged Immunisation Service (SAIS). Only those existing vaccination sites who have been sub-contracted or reached agreement with their NHS England regional team should commence vaccinating this cohort. This includes PCN Groupings.

For the vaccination of children aged 12 to 15 years with underlying health conditions or who are household contacts of severely immunosuppressed patients, and young people aged 16 to 17 years, the following applies to roving and mobile models:

- All providers must meet the same requirements (including contractual, those set out
 in the workforce consideration and clinical red lines document, and the selfassessment readiness checklist Part A and Part B) for vaccinating children and
 young people in the roving and mobile models as these apply to the designated
 vaccination base site.
- Vaccination of children aged 12-15 who are clinically extremely vulnerable (CEV) or household contacts of severely immunosuppressed patients³ (cohort xiii): The Green Book states that "in secondary school age children, information leaflets should be available for the young person's own use and to share with their parents prior to the date that the immunisation is scheduled". This information standard requirement currently means that the information must be shared in advance with patients and their parents/carers/guardians before they attend the vaccination pop-up or walk-in site. Roving vaccination of housebound children cohorts is permitted subject to meeting the information standard as well as clinical, and contractual requirements.

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³ Eligibility criteria for children and young people aged 12 to 15 years outlined in this JCVI guidance from 4 August 2021 and JCVI guidance on vaccination of children aged 12 to 15 years old with underlying health conditions (3 September) in which the definition of underlying health conditions was expanded.

Vaccination of children and young people aged 16-17 ¾. LVS sites (CP and PCN-led sites), Hospital Hub/Hospital Hub+ and Vaccination Centres can vaccinate young people aged 16-17 ¾ and 17 ¾ to 18 years at a roving/pop up site subject to the agreement of the local commissioner and meeting contractual requirements.

3.5 Phase 3 – Booster vaccinations

The <u>JCVI</u> issued guidance on a booster vaccine dose that is to be offered "no earlier than 6 months after completion of the primary vaccine course, in the same order as during Phase 1, with operational flexibility exercised where appropriate to maximise delivery".

As outlined in <u>our letter</u> (15 September 2021), the booster programme will be delivered alongside existing requirements of an evergreen offer to those who have not yet had their first or second dose, vaccinations for eligible 12-15 year olds and third doses as part of the third primary vaccination course for immunosuppressed individuals. For the provision of the evergreen offer and Phase 3, the Enhanced Service Specification: <u>COVID-19 vaccination programme for general practice</u> (GP-led vaccinations only), Local Enhanced Service Agreement: <u>COVID-19 vaccination programme for community pharmacy</u> (community pharmacy-led vaccinations only) and the <u>Service Specifications: Vaccination Centres</u> (including Hospital Hubs) define the scope of the vaccination offer to be provided through the respective delivery model.

Sites that have been regionally assured and are compliant with the contractual, clinical and prescribing requirements can consider delivering booster vaccinations via roving and mobile models. Further requirements for Phase 3 are in our letter.

Additional considerations for all roving and mobile models

4.1 Vaccines

All vaccine movements must be in line with the MHRA conditions of authorisation or summary of product characteristics for the product and the Specialist Pharmacy Service SOPs such as the transportation SOP, conditions set out in the position statements and with the oversight of the chief pharmacist and under the guidance of the pharmacy team.

Movement of vaccines - hierarchy of risk

When considering the use of Pfizer/BioNTech (Comirnaty®) or Moderna (SpikeVax®) in these delivery models, it is critical to ensure the integrity of the vaccine. Transport should always be kept to an essential minimum, cold chain maintained during transport and vials should be packed securely to minimise movement and shaking and to ensure they remain upright and protected from light. Staff at all sites should discuss their plans with their clinical leads and responsible pharmacists as appropriate prior to undertaking transportation of any vaccine type.

Microbial contamination

The movement of punctured vials of COVID-19 vaccine between multiple sites presents a greater risk of microbiological contamination and proliferation than a single site delivery. The SPS SOPs aim to balance the need to protect vaccine quality, minimise the risk of harm to the patient and minimise vaccine wastage so these should be followed.

When planning a vaccination session in a roving or mobile model, risk reduction measures should be put in place and further information is available here; these measures apply to all COVID-19 vaccines.

Cold Chain Management

Some vaccines are inherently unstable when unfrozen or when agitated so maintaining the correct cold chain, preparation technique and transport requirements is critical to maintaining the integrity and effectiveness of all vaccines.

Vaccines must be transported only in approved and validated cool boxes. The temperature of the cool box and contents must be monitored by continuously use of a data logger and reviewed before use. Means of detecting when a temperature excursion has occurred are required and all temperature excursion recordings must be addressed promptly and appropriately, and a full audit trail maintained.

Freezers, gel packs and cool boxes (<u>roving Supply Inventory List 'SIL</u>') will be provided from national stock to the base site. A fridge to hold the vaccine (for VC sites depending on regional arrangements) will be provided to maintain the cold chain during the duration it is

stored at the mobile or roving site. In order to prepare for the cool boxes, the freezer must be active for 24 hours before use. In addition, gel packs require 24 hours cooling before use. Sites should prepare for 48 hours for cold chain preparation (24 hours, freezer commissioning, and 24 hours for gel packs).

Further information on cold chain management: <u>Cold chain SOP & recommendations</u> <u>around transporting in a cool box</u>, and <u>Cool Box Quick Reference Guide: COVID-19</u> Vaccines.

Avoiding waste is a high priority. Vaccines that have not been transported or stored correctly may be ineffective or in the case of incorrect preparation technique, harmful; they must not be used. This stock should be quarantined at the appropriate temperature and reported https://example.com/though-PHE Clinical Advice Response Service.

Unopened vials of vaccine

Returning any unopened vials of vaccine into stock at the designated vaccination base site at the end of the day is only permissible if the following are in place:

- It has been agreed specifically in advance by the base site Lead pharmacist and the system lead pharmacist.
- Every effort is made to minimise the need to return vials to stock by proactively
 matching the number of vials sent to site against the number of patients booked to
 attend each day.
- The designated vaccination base site lead pharmacist understands they are
 assuming personal responsibility and accountability for ensuring cold chain integrity
 and robust stock management for the entire supply chain at all times.
- Both sites can evidence previous successful cold chain management of the vaccine.
- If there have been any previous cold chain breaches on either site, the regional chief pharmacist has adequate assurance that steps have been taken to minimise the risk of recurrence.

Multiple vaccine handling requirements

The <u>SOP for the safe practice for handling multiple vaccines</u> describes how to manage the different vaccines safely. For roving and other mobile vaccination delivery models, the use of the COVID-19 vaccine must be assured through the site lead pharmacist and the system with the region.

COVID-19 Vaccine Oxford/AstraZeneca (AZ)

The <u>JCVI guidance on the booster vaccine</u> outlines the use of AZ in the booster programme.

The MHRA conditional marketing authorisation for the AZ vaccine must be met. The AZ 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 this in-use period. Guidance for transporting this vaccine is available in the SPS SOP: transporting vaccine from PCN designated sites to end user locations.

CP 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). The commissioner needs to record this and inform the national team.

COVID-19 Pfizer/BioNTech (Comirnaty®)

Updated handling and storage requirements now allow the transport of Pfizer/BioNTech for mobile or roving delivery models across PCNs, VCs, and HHs. In order to transport the vaccine safely the following criteria should be in place:

- 1. Transport of undiluted vaccine: Pfizer/BioNTech is to be transported within the one month (31 days) timeframe, at 2-8°C, provided that the travel does not exceed a journey time of 12 hours. There is now no limit on the number of journeys. The onemonth (31 day) shelf life starts when the frozen vaccine is removed from the wholesaler's ULT freezer. For PCN and CP-led sites, this calculation needs to include the journey time from the wholesaler to the site. After first delivery at 2-8°C to the NHS by the Specialist logistics provider, onward transport should always be kept to an essential minimum and vials should be packed securely to minimise movement and shaking. See this guidance for transporting the Pfizer/BioNTech COVID-19 vaccine from PCN-designated sites to end user locations. To help sites understand the remaining travel time available for use within the NHS, our Specialist logistics providers will typically deliver all Pfizer products to primary care sites within 10 hours maximum and will inform sites if their transit time has exceeded 6 hours. This leaves a minimum of 2 hours for onward transportation of undiluted vaccine within the NHS if required (e.g. to pop up sites).
- 2. **Transport of diluted vaccine**: If it is essential to transport a vial *after* dilution, such as when moving it between the homes of housebound patients, it should be in a cool box at 2-8°C and the vial must be used within 6 hours of dilution. If a vaccinator has in their possession diluted (punctured) and undiluted vials it is essential that they are stored and transported separately to avoid the risk of confusion.
- 3. **Compliance** with the storage and handling MHRA conditions of authorisation or conditional marketing authorisation (for the Comirnaty® product) must be met.
- 4. **Cold chain management** requirements see below.
- 5. **No previous cold chain breaches** have been recorded for the base site. If the site has experienced any cold chain breaches, further checks are required before vaccine delivery through the mobile operating model can be approved. The lead

responsible pharmacist (according to site type, this can be the CCG chief pharmacist for PCNs, or the provider trust chief pharmacist) has the responsibility to provide oversight and assurance that steps have been taken to minimise the risk of further cold chain breaches and that the vaccine is able to be transported safely.

In order to carry out roving vaccinations in care homes in the first instance, 6-dose vials from the 1170-dose vaccine pack of COVID-19 mRNA Vaccine Pfizer/BioNTech
(Comirnaty® mRNA Covid-19 Vaccine) can be extracted. In due course, we may be able to offer your site the opportunity to order 90-dose packs of vaccine to visit a single large care home.

mRNA Covid-19 Vaccine Moderna (SpikeVax®)

The <u>summary of product characteristics</u> for the Moderna vaccine have now been updated and allow transport of the vaccine as per the storage and handling requirements. The above criteria outlined for the Pfizer vaccine would apply to the Moderna vaccine also. Transportation at 2-8°C of unopened vials in multiple journeys up to 12 hours in total is now permitted. If it is essential to transport a vial after first puncture it should be in a cool box at 2-8°C and the vial must be used within 6 hours of first puncture. If a vaccinator has in their possession punctured and unpunctured vials it is essential they are stored and transported separately to avoid the risk of confusion.

Table 2: summary of delivery models and vaccine options

Models	Mobile models	Roving model	Drive-through
Storage of vaccine following supply by base site (e.g. the designated PCN/CP-led site)	Provision of validated vaccine storage, preparation and administration areas	Vaccines transported and stored in continuously monitored cool boxes packed at the base site	Provision of validated vaccine storage, preparation and administration areas
Preparation	Dedicated preparation area	Dedicated preparation area	Dedicated preparation area
Administration	Dedicated administration area	Administration in end- user location	Administration in service user car
Onward transport of vaccine	Single vaccine movement from vaccine site base	Multiple movements during shift following supply from vaccine site base	Single vaccine movement from vaccine site base; Movement within site
Appropriate vaccine	AZPfizer/BioNTech or Comirnaty®	AZPfizer BioNTech (or Comirnaty®)	AZPfizer/BioNTech or Comirnaty®

(NB additional		
preparation space and		
waiting area required)		

 Moderna (NB additional waiting area required) (NB additional preparation space and waiting area required)

• Moderna
(NB additional waiting area required)

(NB. additional preparation space and waiting area required)

 Moderna (NB additional preparation and waiting area required)

4.2 Equipment, consumables and personal protective equipment (PPE)

For LVS sites, for Phase 1 and 2 of the vaccination programme, vaccine-related and non-vaccine-related consumables are supplied nationally free of charge.

For LVS sites for Phase 3 all non-vaccine related consumables must be sourced and funded by individual vaccination groups (Primary Care Network / Community Pharmacy). CP- and PCN-led sites that have not signed-up for Phase 3 will get nationally sourced consumables until the end of October. 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 from central funding, where these have been agreed in advance. Further guidance on funding is available for PCN and CP providers on FutureNHS.

The Supply Inventory List (SIL) is a centrally supplied generic equipment and vaccine-related consumables list, providing what is needed to effectively administer vaccinations. The volume of vaccine-related consumables supplied is proportionate to the number of vaccines and is replenished automatically with each vaccine delivery; designated sites are not required to order items on the SIL. Sites are required to order non-vaccine related consumables.

For Vaccination Centres/Hospital Hubs for Phase 3, sites will switch on to a new pull model to order consumables and PPE via the BAU supply channels of their trusts. If required, a provider can request an additional roving SIL from NHS England via the Unipart Helpdesk.

For drive-through clinics, the items required will depend on whether the drive-through clinic will be held at the vaccination base site or at an alternative location. If the latter, some of the additional items provided with the roving Supply Inventor List (SIL) will be required. Additional materials that may be necessary to operationalise drive-through clinics e.g. canopies, drive-through clinic-specific PPE e.g. hi-vis jackets will not be supplied by the national team and should be sourced locally, for example by commissioners seeking mutual aid.

4.3 Infection prevention and control (IPC)

IPC precautions must be maintained by all staff in all settings at all times. Please refer to the latest PHE <u>IPC guidance</u>, the <u>Health and Safety Executive guidance on making your workplace COVID-secure</u>, government guidance on working safely during coronavirus (<u>COVID-19</u>), guidance on how to stay safe and help prevent the spread and guidance on the wearing of <u>face coverings</u>.

For roving vaccinations to the homes of housebound patients, there are additional IPC considerations:

- teams must put on appropriate <u>PPE</u> before accessing the home, and follow guidance on guidance <u>on how to stay safe and help prevent the spread</u>.
- on leaving the site, PPE should be removed and disposed of as outlined in the COVID-19 waste management SOP.

4.4 Reporting

Vaccinations in roving and mobile models should be reported through the base vaccination site (e.g. the designated PCN/CP-led site), as part of their normal reporting requirements. Additional considerations might be required for reporting vaccination events, e.g. for people without an NHS number to aid Point of Care (PoC) entry.

4.5 Quality assurance

Building on the initial site and service assurance, the effectiveness of outreach measures should be monitored. It is advised that this draws on different sources of information including from systems and local authorities to monitor performance and maximise effectiveness of roving and mobile models to increase vaccination uptake (e.g. among people who may experience barriers to accessing health services).

4.6 Contractual and other requirements

- Vaccinations administered should be recorded via the usual PoC system (for example Pinnacle/Outcomes for Health)
- Sites should use the same ODS code that is used to record vaccinations from the respective vaccination base site. For LVS sites, the base site is referred to as the 'designated site'.
 - For LVS sites this will be the vaccination site ODS code. Additional flags such as 'other residential settings' can only be used in appropriate circumstances – for further

- guidance see the <u>PCN Finance and Payments Guidance 2021/22</u> and the <u>Community</u> Pharmacy Financial Guidance COVID Vaccination Programme.
- For HH/HH+/VCs, for temporary or mobile non-residential sites, PoC accounts of the parent site should be used. If pop-ups are a regular feature, these should be encouraged to go through programme assurance as satellite sites, and will be offered standard T&D onboarding.
- For VCs, if the VC Lead Provider sub-contracts a mobile or roving service out of a VC, site Leads/Providers using Pinnacle will need to produce/use POC reports to identify the activity undertaken by the roving sub-contractor. This is to ensure that sub-contractor activity as part of the financial reimbursement or any associated contractual performance management can be recorded.
- An exception to the above is that for SAIS providers, Foundry and site management may necessitate allocation of additional ODS codes and accounts.
- To reduce errors, paper-based recording of vaccination, with subsequent transfer of data, is only to be used by exception when there is no alternative.
- Security and insurance: providers must follow the usual requirements set out for the
 respective delivery operating model. They should liaise with the host site, local resilience
 forums and the police to put in place any reasonable security requirements for the
 provision of the vaccination service. The host site will be responsible for maintaining
 public liability insurance for the host venue. Vaccine and related consumables should not
 be stored at the venue overnight.
- State indemnity (non LVS providers) in relation to clinical negligence for NHS trusts and independent members of CNST which have agreed arrangements with NHS Resolution applies to vaccines given as part of the national COVID-19 vaccine deployment programme regardless of location, and extends to Phase 3. Please note exceptions for Independent Sector (IS) providers. Where clinical negligence indemnity is provided by another provider, confirmation must be sought to confirm that this extends to vaccinations in other locations.
- Indemnity: For PCN-led sites where vaccinations are administered in line with the General Practice Enhanced Service specification, indemnity for clinical negligence will be provided under the Clinical Negligence Scheme for General Practice (CNSGP). This applies to all staff who are employed or engaged by a general practice to deliver the vaccination programme. This indemnity is not dependent on the location in which the services are being delivered.
- Indemnity: For Community pharmacy-led sites state indemnity is not available for Phase
 3. Providers should ensure they have appropriate cover. Where clinical negligence indemnity is provided by another provider confirmation must be sought to confirm that this extends to vaccinations in other locations.

Additional considerations for LVS providers

For the movement of vaccines, for PCN- and CP-led sites the contractual and operational principles set out in the <u>letter of 7 January</u> apply.

Movement of vaccine beyond the Designated site is possible but should only be undertaken where permitted and to increase access and equity of uptake. Circumstances in which this is possible include vaccination of care home patients and staff, vaccination of housebound patients, or temporary vaccination clinics being run by the PCN grouping. Other limited movements of vaccine to third party NHS organisations may also be undertaken in line with the NHS England Mutual Aid policy. Sites must ensure they follow the advice set out in the NHS Specialist Pharmacy Service SOPs.

For all LVS sites, the administration of COVID-19 vaccinations at these locations will only occur where there is a specific reason for the location, which may include (but is not limited to):

- eligible patients are unable to travel to the Designated site
- the population being accessed would otherwise be defined as hard to reach
- to reduce health inequalities.

LVS providers may agree with the Commissioner to deliver a "pop-up" clinic, and the written agreement with the commissioner should include agreement on:

- responsibility for transport/storage of the vaccine
- responsibility for the clinical model, and

at all times, the provisions set out in the <u>General Practice COVID-19 Enhanced Service</u>
<u>Specification</u> and PCN Collaboration Agreement remain in force including that the practices are operating as a temporary single medical practice and they are considered joint and several owners of the vaccine.

Co-administration of COVID-19 vaccine and influenza vaccine

Where the Primary care contractor considers that it is operationally expedient and clinically appropriate to do so and the contractor is signed up to the relevant enhanced services, the COVID-19 vaccine and the seasonal influenza vaccine may be co-administered. Co-administration must at all times be in line with the provisions set out in the Green Book. The JCVI have advised that "the COVID-19 booster vaccine programme should not disrupt or delay deployment of the annual influenza vaccination programme". Therefore, it is important individuals are offered their COVID-19 and influenza vaccine as soon as they are eligible, rather than delaying for the purpose of co-administration. We recognise there will be some instances where a short delay will ensure that more individuals receive both vaccines, for example in care homes, and sites should use their discretion to maximise these opportunities.

For roving vaccinations in older adult care homes and other residential settings:

- CP contractors may be asked by commissioners to vaccinate in care home settings and vaccinate housebound patients where they identify a gap in likely provision.
- The Phase 3 Enhanced Service for General Practice 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. PCN groupings, and in some cases community pharmacies when requested by NHS England, will need to deliver vaccinations in other residential settings where it would not be possible for these patients to attend vaccination sites, as per the General practice phase 3 enhanced service specification and community pharmacy local enhanced service specification. In addition to the £12.58 Item of Service fee, a £10 supplement is payable to LVS providers for each vaccination dose administered to the following groups as per the terms set out in the Phase 3 General Practice enhanced service specification and the community pharmacy local enhanced service specification:
 - Residents in older adult care homes who receive the vaccination at a care home
 - Eligible residents in other residential settings such as care homes for people with learning disabilities or mental health problems, where it is not possible for these patients to attend vaccination clinics
 - Staff in older adult care homes and other residential settings such as care homes for people with learning disabilities or mental health problems or hostel/hotel accommodation for the homeless who receive the vaccination at that care home or residential setting
 - Housebound patients.

More information is in the finance guidance for <u>PCN-</u> and <u>Community Pharmacy-led sites</u> and <u>in our letter of 4 February 2021</u>.

For setting up temporary vaccination clinics:

- For practices/PCNs, the operation of temporary vaccination clinics will be covered under the <u>COVID-19 Vaccination Programme 2020/21 Enhanced Service Specification</u>, and payment for the delivery of this service model will be under the terms of the <u>COVID-19</u> <u>vaccination enhanced service specification</u> and conditional on meeting the requirements set out during the assurance process. Practices/PCN groupings must continue to meet the requirements of the <u>COVID-19 vaccination enhanced service specification</u>.
- CP contractors must be approved by their regional team and commissioner to provide vaccinations at a venue other than the Designated Site within 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. CP contractors must continue to meet the requirements of the Local Enhanced Service in place at that time.

- For drive-through clinics at an alternative location other than the designated site, and temporary vaccination clinics ('pop-ups'), providers will also need to extend their CQC licence under the temporary provision to register the additional venue. Further <u>guidance</u> for local commissioners can be found in our letter (24 February 2021).
- CP contractors must ensure they can comply with General Pharmaceutical Council (GPhC) standards and should refer to the GPhC guidance for providing COVID-19 vaccination.

5. Vaccinations

5.1 Consent

The legal position and standards expected of healthcare professionals by their regulatory bodies on obtaining consent before administration of all vaccines are in Chapter 2 of the Green Book.

Further information on vaccine safety and effectiveness is available from the <u>MHRA</u> website. Information for the public is available <u>here</u>.

Where it has been established that the person lacks capacity to consent, a best interests decision should be taken in line with the checklist in section 4 of the Mental Capacity Act.

There is no legal requirement for consent to the vaccination to be in writing, however, the consent process and any decision must be documented to serve as a record of the decision and the discussions that have taken place. Relevant consent forms, other supporting forms and associated information are on the GOV.UK website.

The Consent briefing has been updated to include the requirements around consenting **children and young people** and specific information around consent within the national protocol framework. The guidance is available <u>here</u>.

5.2 Clinical review and delivery of vaccination

Prior to vaccination, the patient must be assessed for their suitability for vaccination. The <u>Green Book: Immunisation against infectious disease</u>, JCVI guidance and any COVID-19 vaccine specific guidance should be followed. Screening questions are included in the Point of Care IT systems to support the clinical assessment and consent process.

All clinical teams should ensure they have completed the relevant vaccine training including familiarising themselves with the contraindications and cautions for each of the vaccines being administered and ensure that patients who present for vaccination are asked about

any relevant risk factors. Screening questions that include the contraindications and cautions for each of the vaccines are included in the point of care systems (PoC) and therefore it is recommended that the PoC IT systems are used during a patient consultation and not completed afterwards. Further information is available in the MHRA Summary of Product Characteristics for each vaccine. The provider must ensure that appropriate policies, procedures and training requirements are met, and staff should be present on-site during operating hours to discharge these functions.

Providers must ensure all staff are aware of the <u>escalation processes for clinical incidents</u> and <u>enquiries</u>. This should include reporting any suspected vaccine side effects or adverse incidents to the MHRA via the <u>Coronavirus Yellow Card reporting site</u>.

NHS.UK provides advice on clotting symptoms for vaccine recipients.

5.3 First aid and resuscitation preparation

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

For the vaccination of children and young people, providers need to ensure that additional requirements are met as outlined in the self-assessment readiness checklist Part A and Part B.

All mobile teams should at a minimum include a registered healthcare professional trained within the previous 18 months in the management of anaphylaxis and cardiopulmonary resuscitation.

Access to an automated external defibrillator (AED) for roving vaccinators is unlikely to be required in most cases, but this should be based on a local risk assessment considering the following:

- Population at risk; the numbers and types of patients being vaccinated, with older patients likely to be at higher risk of cardiac arrest in general.
- Distance from medical support and the ability to deploy a defibrillator in a very short time (minutes), i.e. location of the nearest publicly available AED which can be found at https://www.heartsafe.org.uk/aed-locations. Where a public access defibrillator is available, all staff should be trained in how to use it.

Access to oxygen for roving vaccinators should be determined by individual risk assessments, and considering the number of patients to be vaccinated during the visit.

The provider must ensure that basic lifesaving equipment and supplies for the management of potential adverse drug reactions (including anaphylaxis) are present during all hours of

operation. All mobile teams will be provided with resuscitation equipment and medications via the <u>Supply Inventory List</u> (SIL).

Some teams may wish to have additional equipment or medicine as recommended by the Resuscitation Council UK and can complete a local resuscitation risk assessment. PHE has included resuscitation training within its COVID-19 vaccination programme training resources.

5.4 Patient experience

Providers should make information available for patients who wish to compliment, comment, or complain about the service.

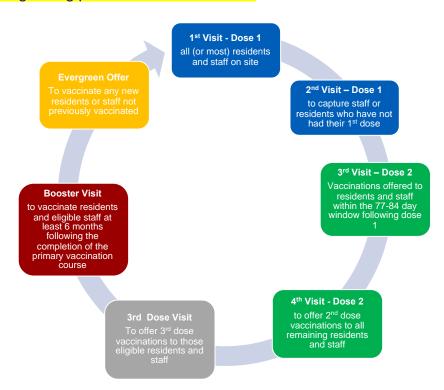
Providers should provide opportunities for patients from all communities to discuss vaccination concerns ahead of their vaccinations. This should be supported by access to translation services to support the patient experience.

Appendices

Appendix A: Roving visit schedule and workforce set-up for care homes

Visit schedule: 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.
- 2nd visit to capture staff or residents who were unavailable on the day and who have not had their 1st dose.
- 3rd visit dose 2 vaccinations offered to residents and staff within the JCVI recommended interval following the 1st dose. New residents and staff who have not had their 1st dose should also be offered the vaccine at this visit.
- 4th visit to capture outstanding 2nd doses one week later.
- 3rd primary dose visit JCVI guidance advises that a third primary dose be offered to individuals aged 12 years and over with severe immunosuppression
- Booster visit to vaccinate residents and eligible staff on site, at least 6 months following the completion of the primary dose vaccination course
- Evergreen offer regular follow-up visits may be required to vaccinate any new residents or social care workers not previously vaccinated. Providers should agree an ongoing rolling process with care homes



Guidance on vaccinating in care homes with COVID-19 cases is <u>here</u>. The Social Care Workers SOP provides further guidance here.

The following set-up is recommended for care homes and, as a guide, a single vaccinator may achieve 30 vaccinations per half-day:

- 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).

Appendix B: Assurance checklist developed for the St John Ambulance mobile treatment unit pilot

SJA mobile treat unit



SECTION ONE: HUB SITE DETAILS

Name, email and phone number of person completing this document	
Name of hub site	
ODS Code of hub Site	
Name of Site where the mobile vehicle will be parked	
Address of hub site	
Contact Name and phone number for hub site	
Indicative number of vaccinations site is expected to deliver on the day of operation	
Date(s) when the SJA Mobile Units will be operation	

SECTION TWO - ASSURANCE CHECKLIST

Please use the drop-down (Y/N) option to indicate whether a specific requirement has been met by the nominated Hub site in agreement with PCN .

	Criteria	Requirements	Requirements Met YESINO
	Sufficient vaccine requested to supply mobile unit		
1	Hub Site	Sufficient IT kits and clinical supplies acquired	
		Workforce booked and available to be deployed for the agreed sessions	

Continued SECTION TWO – ASSURANCE CHECKLIST



		Ability to flex capacity to deliver on different days of the week between 08:00hrs and 20:00hrs including weekends and bank holidays where applicable to target low update and vaccine availability	
		Capacity and capability to coordinate with the CCG/PCN/Hub Site to plan clinics according to expected vaccine supply and cohort demand	
		Capacity and capability to coordinate the required appropriately trained workforce to meet different demand on operational days	
	report 10 Sec. 1	Ensure that appropriate vaccine and associated consumables are available for clinic days	
2	Planning and Co- ordination	Safely and securely deploy the vaccine from the Hub site/LVS Designated site to the Mobile Unit at the Hub site and return any unused vaccine to the Hub site/LVS site at the end of the day, maintaining the cold chain and in line with national guidance for movement of AZ vaccine	
		Amend the clinic schedule if there is any disruption caused by adverse weather conditions/vaccine supply/workforce/equipment failure and undertake timely communications with booked patients, Hub site/LVS, and Estates Team	
		Ability to ensure patients are booked in for their second vaccine dose at the same site/venue and in line with national guidance	
3	Site Safety	Ability to ensure smooth entry and exit from the site complying with social distancing and current COVID-19 guidance, with appropriate security arrangements, providing stewards if needed and ensuring that there are adequate car parking facilities	
		Ability to comply with required assurance process to deliver vaccination clinics from the Mobile Unit	
4	Mantana	Ability to plan and deliver clinics with no wastage	
4	Wastage	Ability to ensure appropriate disposal of all clinical waste	
		Know how to liaise with the lead employer/SJA to access any additional workforce requirements	
5	Workforce	Ensured that any non-registered staff administering vaccines are working under clinical supervision and in compliance with national protocols	
		A clear plan is in place to provide adequate staff for the Mobile Unit clinics	





	Patient	Information is provided in appropriate formats and languages to meet different needs including vaccine advice and decision support, pre/post vaccination materials and access to information online.	
6	Experience	Patients with additional needs are supported, including access, language, communication needs	
		Patients, carers, volunteers, staff and the Hub site are encouraged and provided with the opportunity to feedback on their experience	
7	7 Vaccine storage and handling allowable time at 2-8c before administration and time between dilution and administration.		
		Appropriate space and trained workforce to prepare the vaccine, using standard aseptic technique, and drawing up of multi-dose vials in all cases	
9 Administration Ability to administer vaco		Ability to administer vaccines safely in accordance with IPC guidance in all settings	
10	Aftercare	Ability to provide post-vaccination observation, compliant with social distancing and with access to necessary equipment and trained staff to provide immediate response to an adverse event	
		Comply with point of care data collection requirements including Pinnacle	
11	Data collection	There is appropriate access to the relevant system to record the vaccination event the same working day as the vaccine administration occurs and that all staff are trained and have the relevant access to support timely data collection.	
12	Reporting	Contribute to assurance assessments; monitoring, reporting and responding to the early warning triggers and mitigation; reporting incidents; responding to daily and hoc requests for intelligence and information.	

SECTION THREE - TO BE COMPLETED BY CCG REPRESENTATIVE



Date assessment completed	
Name and job title representative completing assessment	
Email and phone number representative completing assessment	
On the basis of the assessment, has the nominated site met all of the designation criteria?	

Appendix C: Drive-through configuration for a vaccination centre

For vaccination centres, an example drive-through configuration could be:

 i) Fridge 2-8 ° (in secure area) ii) Back-up fridge in case of power/fridge failure iii) (Separate fridges in case of multiple vaccines) 	Drive-through with a small pharmaceutical fridge housed in a powered marquee. Fridge to remain in marquee, but vaccines removed overnight (ensure vaccine doses are used up before this). Appropriate number of vaccines to be transported to drive-through site from base site each morning in cool bags as outlined in the clinical SOP on maintaining COVID-19 vaccines cold chain.
Security	24/7 security; Police should be informed about drive- through, site security including OOH.
Toilets and handwashing facilities	Solutions such as porta-cabin with toilets required at site.
Workforce	In line with requirements set out in legal mechanisms for administering a Prescription Only Medicine (POM), National Protocols; PGDs; and local PSDs, including appropriate supervision of non-registered vaccinators; workforce welfare and OOH requirements.
Protocol for emergency response	Guidance in section 5.3, considerations for availability of oxygen, defibrillator and anaphylaxis packs, emergency access for ambulance, training requirements for RHCPs. Advising people to unlock their car doors in advance in case clinical team needs to provide any clinical support – this may require signage at check in.
Internet access and availability	Ensure Point of Care system access, patient care records
of IT/Equipment	access, 4G/Wi-Fi availability.
Robust consent and recording process	As outlined in section 5.1.

Process and flows

Signage	Cars will be triaged and directed into drive through ensuring confirmation of eligibility of service user.
Separate entrance/exit	One-way system in place.
Check-In	Confirmation booking and eligibility.
Space for post-vaccination	Provision made for post-vaccination observation; separate
observation for 15 mins+	lanes to ensure flow will not be disrupted.
Post-vaccination	Information provided to patient, including information on
	· · · · · · · · · · · · · · · · · · ·

	and additional vaccine specific information (i.e. leaflet informing about rare events of blood clots for AZ).
Equity of access	,

Additional needs	Any service user with additional needs is to be re-directed
	to base site, i.e. vaccination centre.

For vaccination centres, an example end-to-end user journey for adult cohorts could be⁴:

Access: all users will enter the site through the designated entrance where eligible patients will be identified. Signs and marshals can assist in guiding patients.

Check-In: in line with existing processes outlined in the VC Operating Framework.

- For drive-through clinics, screening processes to identify patients visiting for their first or second dose, and eligibility for drive-through vaccination, can support the operational flow.
- Following check-in, users will be directed to join a gueue. Users will be asked to unlock their car doors to facilitate immediate access in the event of a clinical emergency. Registered healthcare professionals will work their way down the queue, completing the clinical assessment.

Screening and recording of vaccination event data in line with existing guidance.

Consent discussion in line with existing guidance summarised in section 5.1.

Clinical review: Providers should consider completing an initial clinical review to assess the individual's suitability for vaccination prior to attending the clinic if possible; this should be repeated prior to vaccination as set out in section 5.2.

Vaccination will be in accordance with existing guidance and as set out in section 3.

Clinicians and vaccinators can use trollies, with each having a small sharps bin for the secure and safe disposal of needles post vaccination.

Post-vaccination observation and adverse reactions: Follow guidance in section 4.1.

For the AZ vaccine, there is no requirement for the vehicle or its occupants to remain *in-situ* post vaccination. Unless clinical assessment indicates it or when the driver of the vehicle has been vaccinated.

⁴ Guidance informed by SOP RD&E VC drive-through

For the Pfizer/BioNTech (Comirnaty®) vaccine, a 15-minute period of post-vaccination observation is required for everyone, regardless of driving status. The vehicle must remain *in-situ* post-vaccination for the recommended time period.

For the Moderna (SpikeVax®) vaccine, a 15-minute period of post-vaccination observation is required for everyone, regardless of driving status. The vehicle must remain in-situ post-vaccination for the recommended time period.

The provider should ensure that appropriate provisions are in place for vehicles to remain stationary for this period without interrupting the flow of subsequent vehicles. One solution is the provision of one or more parking areas where patients will receive their vaccination and that are separate from and will not block entrance and exit points.

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.

For providers not electing to have paramedic or ambulance provision on site it is recommended that the local ambulance provider is sighted during the planning phase.

Appendix D – Checklists for temporary vaccination clinics operated by PCN-led and community pharmacy led sites

This guidance was communicated to vaccination sites on 24 February 2021 here.

NHS England through its regional teams may commission the temporary vaccination clinic under the terms of the Enhanced Service Specification (for GP practices collaborating in a PCN grouping) or the Local Enhanced Service Specification (for Community Pharmacy) and will confirm in writing with the provider the arrangements, which should include:

- A definition of the population who will be invited to take up vaccinations at the temporary vaccination clinic and which must be restricted to currently eligible and authorised cohorts. If this is likely to include eligible patients who are registered with another practice outside the PCN grouping that is being commissioned, the commissioner should try to inform the practices concerned that this additional choice is being made available to enhance uptake levels.
- Confirmation of how patients will be invited to the clinic.
- Confirmation of any other providers who will be vaccinating at the venue and the
 agreed schedule they will work to. The capacity of individual venues and preferred
 local arrangements will guide whether multiple providers can use the space at the
 same time but this is unlikely to be advisable.
- A definition of the timeframe for when the clinic will be set up, on which dates and the agreed stand down date.
- Assurance that where required, equipment will be provided locally.

If a provider is commissioned to deliver COVID-19 vaccinations from a temporary vaccination clinic:

- The provider would receive £12.58 per vaccination delivered at these clinics under the terms of the <u>Enhanced Service Specification</u> and <u>Local Enhanced Service</u> Specification (for community pharmacies).
- Second dose clinics will also need to be scheduled at the same venue within the required time period.
- It is anticipated that the venue itself would, in most cases, be available free of charge but some running costs may be reimbursable if VFM requirements are met. These costs will be funded through the Reasonable Additional Costs funds which must be agreed by CCGs and local commissioners and paid through regions. The guidance for these payments for PCN sites can be found here on the FutureNHS Collaboration Platform. The guidance for Community Pharmacy sites can be found <a href=here.

Providers are encouraged to use the Licence to Occupy template available on NHS Futures. Buildings insurance will be covered by landlords, contents insurance should be taken out by tenants.

Providers are also encouraged to consider whether they need to undertake a security risk assessment. A template is available on NHS Futures.

If the venue is only available for a short period (i.e., 1-2 day), providers would need to use their existing roving kits to deliver the clinics and no further equipment would be provided. If the venue is available and commissioned for a longer period (eg., once a week for 5 months), the provider may request an additional roving SIL from NHS England but should only do so where existing equipment cannot be used. Where it is possible to provide an additional roving SIL, providers should allow 10 days for the SIL to be delivered. If equipment/chairs/tables/screens are needed, commissioners should seek to provide this through mutual aid.

Commissioners should also undertake a visit to ensure the venue meets minimum requirements.

LVS venue checklist

Venues being used for temporary vaccination clinics will not be formally designated as vaccination sites but will still need to meet a set of requirements to ensure they are suitable for vaccine delivery. As a minimum, the venues should be:

- Accessible.
- Available for exclusive use on days agreed with local commissioner for the period they will be in use as a temporary vaccination clinic.
- Able to provide at least c350sqm plus staff/public facilities (ideally, ground floor), with parking on site or close by.
- Able to provide separate entrance and exit points to assist with social distancing and support a natural flow of patients through the building to comply with social distancing guidance.
- Wi-Fi enabled the venue will need appropriate Wi-Fi connectivity depending on the use of the venue.
- Well-ventilated.
- Accessible via local transport or in the local community.

All venues will be assessed on their ability to provide three key areas:

- 1. Arrival and check-in
- 2. Clinical assessment
- 3. Delivery of vaccination there are minimum space requirements for each area.