Standard Operating Procedure: Roving and mobile models

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, PCN-led sites and community pharmacies. They include care homes, the housebound, other residential settings or settings of multiple occupancy, temporary vaccination clinics (eg pop-ups or satellites), 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 with low coverage.

1.1 **General guidance and advice**

This SOP must be read in conjunction with:


- 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](https://www.gov.uk/guidance/the-green-book). Vaccine-specific SOPs are on the Specialist Pharmacy Service website.

- 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.

- Legal mechanisms for administration of COVID-19 vaccine

In addition, the following documents apply:

- Vaccination Centres (VC): [Vaccination Centre Operating Framework](https://www.gov.uk/guidance/vaccination-centres) and POD definition document.


- For PCNs and Community Pharmacies (CPs): [Further opportunities for PCN and Community Pharmacy COVID-19 vaccination sites to partner with community venues to delivery temporary vaccination clinics](https://www.gov.uk/guidance/vaccination-centres).
• COVID 19 Vaccination Programme – Service Specifications: Vaccination Centres (including Hospital Hubs), Service Specifications: Local COVID-19 Vaccination Services.

• PHE resources for communicating with the public are available to sites, including in accessible formats. Further resources are on the FutureNHS Communications and Engagement pages.

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

• Further guidance is on our website and the FutureNHS workspace.

2. Preparing for roving and mobile vaccination

Vaccines, consumables and equipment will continue to be delivered to the respective base sites and need to be transported from there to the mobile vaccination site or end-user location.

IT/hardware equipment to support the vaccination process should be ordered by the base site.

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 should be completed to assess the strategy.

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 processes will be set out by clinical leads (i.e. lead responsible pharmacist) and the region.

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 NBS SOP. Call/recall and booking arrangements should follow the normal process in accordance with JCVI eligibility criteria for vaccination.

All base sites should consider:

- Capacity planning: how roving and mobile site teams will contribute to vaccinating eligible cohorts in their local population and identified targets for the outreach programme.

- Inequalities in vaccination uptake: as a minimum, regions, ICSs and base sites should have used the inequalities tool/s i.e. SHAPE/ geospatial analysis and consulted with local communities to determine the site location.

- The workforce plan required, expected vaccination throughput and respective requirements to deliver vaccinations (i.e. 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

<table>
<thead>
<tr>
<th>Delivery model</th>
<th>Location</th>
<th>Eligible and target cohorts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Roving model</strong></td>
<td>Service provided to small groups or individuals in both NHS or non-NHS sites, including single and multiple occupancy.</td>
<td>Eligible individuals living within <strong>residential sites</strong>, including care and nursing homes and homes for people with a learning disability. 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 <strong>housebound</strong>. Hard to reach groups, including, but not limited to, people experiencing homelessness and traveller communities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Mobile model</strong></td>
<td>NHS and non-NHS sites</td>
<td>Communities identified with low vaccination uptake (&lt;75 per cent of the eligible cohort)$^2$. 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.$^3$</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eligible cohorts as defined in JCVI guidance</td>
</tr>
<tr>
<td><strong>Drive-throughs</strong></td>
<td>NHS and non-NHS sites</td>
<td></td>
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<td></td>
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</tbody>
</table>

- **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.
- **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. Single movement of vaccine during shift from base site to temporary vaccination clinic.
- **Drive-throughs**: 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.
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, people with learning disabilities or mental health problems
- 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 vaccines from locations other than their designated site. LVS providers should work with CCG, ICS, local authority 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 4.11.

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 National Protocols, PGDs, and local PSD, the number 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.
- The consent discussion (see section 5.1). Additional preparation may be needed to support those who live alone or who lack mental capacity. Additional considerations for people with 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 Green Book.

3.2 Mobile models

Mobile models include the temporary installation of stationary vaccination clinics at locations other than the established vaccination base.

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 site base 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 the region.

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 our guidance. Our letter of 7 January outlines the framework for this to take place.

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 if they presented. PCN groupings that have been approved to vaccinate cohorts 10-12 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 vaccination sites, our letter 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.

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. 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 or from appropriate locations other than those which have been specifically established for COVID-19 vaccination.

Local commissioners are encouraged to work with existing contractors to establish drive-through 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.
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 incident.

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.
- 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.

**Drive-through clinics at an alternative location**

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 with their LES agreement. We will amend the LES document to ensure that the nature of those additional venues is at the discretion and approval of the commissioner.
- 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
  - IPC lead
  - Overall site management.
4. Additional considerations for all roving and mobile models

4.1 Vaccines

All vaccine movements must be in line with 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.

The mRNA COVID-19 vaccine Moderna is not considered suitable for mobile operating models.

COVID-19 Vaccine Oxford/AstraZeneca (AZ)

Use of the Oxford/AstraZeneca vaccine to visit housebound patients provides guidance on the safe transport and use of punctured vials. There is also guidance for the use of the Oxford/AstraZeneca vaccine in and between care homes and guidance on transporting this vaccine from PCN designated sites to end user locations, patients’ homes and within the PCN grouping. LVS sites should follow both sets of guidance to ensure safe transfer of vials between all residential settings and aseptic technique.

Whilst this guidance was written for roving models, it is applicable to all mobile vaccination operating models across all delivery models using the AZ vaccine (as outlined in section 3.1 to 3.3, appendices A-C).

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.

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.

Returning any unused AZ vials into stock at the base at the end of the day is only permissible if the following are in place:

- It has been agreed by the chief pharmacist of the base site.
- 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 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.

COVID-19 mRNA Vaccine Pfizer/BioNTech

To allow transport of the COVID-19 mRNA Vaccine Pfizer/BioNTech for mobile or roving delivery models across PCNs, VCs, and HHs the following criteria should be in place:

1. **Availability:** COVID-19 Vaccine AZ is either i) not suitable for the patients that are to be vaccinated or ii) not available.

2. **Transport requirements:** the COVID-19 mRNA Vaccine Pfizer/BioNTech is to be transported within the one month (31 days) timeframe, at 2-8°C, provided that the travel does not i) exceed two journeys of 6 hours each, or ii) one journey of 12 hours. The one-month (31 day) shelf life starts when the frozen vaccine is removed from the wholesaler’s ULT freezer. For PCNs and CPs, this calculation includes the journey from the wholesaler to the site, and the total of two journeys includes the transfer from the wholesaler to the PCN. See this [guidance for transporting the Pfizer/BioNTech COVID-19 vaccine from PCN-designated sites to end user locations](#). The number of journeys that can be made will be dependent on how the Pfizer/BioNTech COVID-19 vaccine is supplied to the base site. Only two journeys can be made once the Pfizer vaccine is defrosted and the vial cannot be transported after dilution. The vaccine can only be moved once from a base to a static site. Once there, it cannot be moved further, nor can it be returned to the base site.

3. **Compliance** with the MHRA conditions of authorisation 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

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1 A mobile treatment centre or a vaccination bus are considered static if they remain at the identified location during a shift and do not move around further.
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.

**Movement of vaccines - hierarchy of risk**

When considering the use of COVID-19 mRNA Vaccine Pfizer/BioNTech in these delivery models, it is critical to ensure the integrity of the vaccine. Reconstituted COVID-19 mRNA Vaccine Pfizer/BioNTech should be carried by hand where possible to avoid shaking, and COVID-19 mRNA Vaccine Pfizer/BioNTech should be drawn-up next to the patient.

**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, and 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 ('roving SIL') 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: [Cold chain SOP & recommendations around transporting in a cool box](#), and [Cool Box Quick Reference Guide: COVID-19 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 through PHE Clinical Advice Response Service.

**Unopened vials of vaccine**

The Pfizer/BioNTech vaccine cannot be returned. Unopened vials of other vaccines can only in exceptional circumstances be returned to the base stock after the second journey and is dependent on the individual vaccine. This must be agreed specifically in advance by the site Lead pharmacist and the regional chief pharmacist.
Multiple vaccine handling requirements

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

Table 2: summary of delivery models and vaccine options

<table>
<thead>
<tr>
<th>Models</th>
<th>Mobile models</th>
<th>Roving model</th>
<th>Drive-through</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage of vaccine following supply by base site</td>
<td>Provision of validated vaccine storage, preparation and administration areas</td>
<td>Vaccines transported and stored in continuously monitored cool boxes packed at the base site</td>
<td>Provision of validated vaccine storage, preparation and administration areas</td>
</tr>
<tr>
<td>Preparation</td>
<td>Dedicated preparation area</td>
<td></td>
<td>Dedicated preparation area</td>
</tr>
<tr>
<td>Administration</td>
<td>Dedicated administration area</td>
<td>Administration in end-user location</td>
<td>Administration in service user car</td>
</tr>
<tr>
<td>Onward transport of vaccine</td>
<td>Single vaccine movement from vaccine site base</td>
<td>Multiple movements during shift following supply from vaccine site base</td>
<td>Single vaccine movement from vaccine site base; Movement within site</td>
</tr>
<tr>
<td>Appropriate vaccine</td>
<td>• AZ</td>
<td>AZ^2</td>
<td>• AZ</td>
</tr>
<tr>
<td></td>
<td>• PB (NB. additional preparation space and waiting area required for PB)</td>
<td></td>
<td>• PB – is not advised as the product is very fragile. If it has to be used, every effort must be made to ensure the product integrity is maintained by following the guidance above relating to vaccine movement (NB. additional preparation space and waiting area required)</td>
</tr>
</tbody>
</table>

^2 PB has been used for roving vaccination of care homes where roving vaccination was limited to one site
4.2 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). 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 base site or at an alternative location. If the latter, some of the additional items provided with the roving 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 IPC guidance, 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 the wearing of face coverings.

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

- Teams must put on appropriate PPE before accessing the home, and follow guidance on social distancing.
- 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 site, as part of their normal reporting requirements.

4.5 Quality assurance

Building on the initial site and service assurance, a mixed method approach can be taken to measure the effectiveness and performance of the roving and mobile models, monitoring vaccination uptake and the impact of the model.

4.6 Contractual and other requirements

- Vaccinations administered should be recorded via Pinnacle/Outcomes for Health
There are different options for recording vaccinations through ODS codes. Sites can use the same ODS code that has been allocated to the respective vaccination base.

LVS providers record against the existing lead practice ODS code of the PCN grouping. Pharmacies will record all vaccinations against the ODS code of the designated site.

HHs or VCs might decide to receive a 'child' ODS code to capture vaccinations at the mobile site, to be able to track vaccination use, efficiency and vaccination waste.

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 in relation to clinical negligence applies to vaccines given as part of the national COVID-19 vaccine deployment programme regardless of location. Please note exceptions for IS providers.

Additional considerations for LVS providers

For the movement of vaccines, for PCN and CPs the contractual and operational principles set out in the letter of 7 January apply.

For roving vaccinations in care homes:

- CP providers may be asked by commissioners to vaccinate in care home settings and vaccinate housebound patients where they identify a gap in likely provision.

- 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. PCN groupings, and in some cases community pharmacies when requested by NHS England, will need to deliver vaccinations in residential settings where it would not be possible for these patients to attend vaccination sites, as set out in our letter of 13 February.

- In addition to the £12.58 Item of Service fee, a £10 supplement is payable to LVS providers for each vaccination dose administered to:
  - Residents and staff in older adult care homes
  - Housebound patients
- Eligible residents and staff in other residential settings, where it is not possible for these patients to attend vaccination clinics.

More information is in the finance guidance for PCNs and Community Pharmacy and in our letter of 4 February 2021.

For setting up temporary vaccination clinics:

- For practices/PCNs, the operation of temporary vaccination clinics will be covered under the COVID-19 Vaccination Programme 2020/21 Enhanced Service Specification (VP ESS) model of care, and payment for the delivery of this service model will be under the terms of the COVID-19 VP ESS and conditional on meeting the requirements set out during the assurance process. Practices/PCN groupings must continue to meet the requirements within the COVID-19 Vaccination Programme 2020/21 ESS and there will be no change to current PCN grouping set-up and supply arrangements.

- 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 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 guidance 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 MHRA website. Information for the public is available from PHE.

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.

5.2 Clinical review and delivery of vaccination

Prior to vaccination, the patient must be assessed for their suitability for vaccination. The Green Book: Immunisation against infectious disease, 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. Further information is in the MHRA information for UK healthcare professionals. 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 escalation processes for clinical incidents and enquiries. This should include reporting any suspected vaccine side effects or adverse incidents to the MHRA via the Coronavirus Yellow Card reporting site.

PHE’s patient information leaflets give 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.

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.

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 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.
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.
- Dose 2 – vaccinations offered to residents and staff within the 56-63 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.
- 4th visit – to capture outstanding 2nd doses one week later.

Guidance on vaccinating in care homes with COVID-19 cases is 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**

<table>
<thead>
<tr>
<th>Name, small and phone number of person completing this document</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of hub site</td>
<td></td>
</tr>
<tr>
<td>Code of hub site</td>
<td></td>
</tr>
<tr>
<td>Name of site where the mobile vehicle will be parked</td>
<td></td>
</tr>
<tr>
<td>Address of hub site</td>
<td></td>
</tr>
<tr>
<td>Contact name and phone number for hub site</td>
<td></td>
</tr>
<tr>
<td>Indicative number of vaccinations site expected to deliver on the day of operation</td>
<td></td>
</tr>
<tr>
<td>Data(s) when the SJA Mobile Units will be operation</td>
<td></td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Requirements</th>
<th>Requirements Not Met Y/N/NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 HubSite</td>
<td>Sufficient vaccine requested to supply mobile unit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sufficient IT kit and clinical supplies acquired</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workforce booked and available to be deployed for the agreed sessions</td>
<td></td>
</tr>
</tbody>
</table>

**Continued SECTION TWO – ASSURANCE CHECKLIST**

<table>
<thead>
<tr>
<th></th>
<th>Planning and Co-ordination</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>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 crew update and vaccine availability</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Capacity and capability to coordinate with the CCG/PCN/Hub Site to plan clinics according to expected vaccine supply and cohort demand</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Capacity and capability to coordinate the required appropriately trained workforce to meet different demand on operational days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ensure that appropriate vaccine and associated consumables are available for clinic days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Safely and securely deploy the vaccine from the Hub site LV5 Designated site to the Mobile Unit at the Hub site and return any unused vaccine to the Hub site LV5 site at the end of the day, maintaining the cold chain and in line with national guidance for movement of AZ vaccine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Amend the clinic schedule if there is any disruption caused by adverse weather conditions/vaccine supply/vaccine equipment failure and undertake timely communications with booked patients, Hub site LV5, and Estates Team</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ability to ensure patients are booked in for their second vaccine dose at the same site/venue and in line with national guidance</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Site Safety</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Ability to ensure smooth entry and exit from the site complying with social distancing and current COVID-19 guidance, with appropriate security arrangements, providing site-ward if needed and ensuring that there are adequate car parking facilities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ability to comply with required assurance process to deliver vaccination clinics from the Mobile Unit</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Wastage</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Ability to plan and deliver clinics with no waste</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ability to ensure appropriate disposal of all clinical waste</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Workforce</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Know how to liaise with the lead employer/UK to access any additional workforce requirements</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ensured that any non-registered staff administering vaccines are working under clinical supervision and in compliance with national protocols</td>
<td></td>
</tr>
<tr>
<td></td>
<td>A clear plan is in place to provide adequate staff for the Mobile Unit clinics</td>
<td></td>
</tr>
</tbody>
</table>
## SECTION TWO - ASSURANCE CHECKLIST

<table>
<thead>
<tr>
<th>No.</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Patient Experience</td>
<td>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. Patients with additional needs are supported, including access, language, communication needs.</td>
</tr>
<tr>
<td>7</td>
<td>Vaccine storage and handling</td>
<td>Ability to fully comply with all storage and handling requirements, including maximum allowable time at 2-8°C before administration and time between dilution and administration.</td>
</tr>
<tr>
<td>8</td>
<td>Preparation</td>
<td>Appropriate space and trained workforce to prepare the vaccine, using standard aseptic technique, and drawing up of multi-dose vials in all cases.</td>
</tr>
<tr>
<td>9</td>
<td>Administration</td>
<td>Ability to administer vaccines safely in accordance with IPC guidance in all settings.</td>
</tr>
<tr>
<td>10</td>
<td>Aftercare</td>
<td>Ability to provide post-vaccination observation, comply with social distancing and with access to necessary equipment and trained staff to provide immediate response to an adverse event.</td>
</tr>
<tr>
<td>11</td>
<td>Data collection</td>
<td>Comply with point of care data collection requirements including Phenacide. 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.</td>
</tr>
<tr>
<td>12</td>
<td>Reporting</td>
<td>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.</td>
</tr>
</tbody>
</table>

## SECTION THREE - TO BE COMPLETED BY CCG REPRESENTATIVE

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date assessment completed</td>
<td></td>
</tr>
<tr>
<td>Name and job title representative completing assessment</td>
<td></td>
</tr>
<tr>
<td>Email and phone number representative completing assessment</td>
<td></td>
</tr>
<tr>
<td>On the basis of the assessment, has the nominated site met all of the designation criteria?</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix C: Drive-through configuration for a vaccination centre

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>i)</strong> Fridge 2-8 ° (in secure area)</td>
<td>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).</td>
</tr>
<tr>
<td><strong>ii)</strong> Back-up fridge in case of power/fridge failure</td>
<td>Appropriate number of vaccines to be transported to drive-through site from base site each morning in cool bags as outlined in the <a href="#">clinical SOP on maintaining COVID-19 vaccines cold chain</a>.</td>
</tr>
<tr>
<td><strong>iii)</strong> (Separate fridges in case of multiple vaccines)</td>
<td></td>
</tr>
</tbody>
</table>

**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 prior in case clinical team needs to provide any clinical support – this may require signage at check in.

**Internet access and availability of IT/Equipment**

- Ensure Point of Care system access, patient care records access, 4G/Wi-Fi availability.

**Robust consent and recording process**

- As outlined in section 5.1.

### Process and flows

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Signage</strong></td>
<td>Cars will be triaged and directed into drive through ensuring confirmation of eligibility of service user.</td>
</tr>
<tr>
<td><strong>Separate entrance/exit</strong></td>
<td>One-way system in place.</td>
</tr>
<tr>
<td><strong>Check-In</strong></td>
<td>Confirmation booking and eligibility.</td>
</tr>
<tr>
<td><strong>Space for post-vaccination observation for 15 mins+</strong></td>
<td>Provision made for post-vaccination observation; separate lanes to ensure flow will not be disrupted.</td>
</tr>
<tr>
<td><strong>Post-vaccination</strong></td>
<td>Information provided to patient, including information on next appointment (if applicable), adverse event reporting.</td>
</tr>
</tbody>
</table>
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 could be³:

**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 queue. 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 5.4.

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.

For the Pfizer/BioNTech 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.

³ Guidance informed by SOP RD&E VC drive-through
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.