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Version 3.2, 14 January 2021

Novel coronavirus (COVID-19) standard operating procedure

COVID-19 local vaccination services deployment in community settings

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

Any changes since v3.1 (6 January 2021) are highlighted in yellow.

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

The latest version of this guidance is available here.

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

Operational queries should be directed to your commissioner.

Version 3.2, 14 January 2021

Contents

1. Scope

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

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

1.1 General guidance and advice

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

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

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

Our guidance and related letters for the COVID-19 vaccination programme can be found on our website, and other helpful resources are available on FutureNHS.

2. Preparation for local vaccination services

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

2.1 Leadership and Governance

Clinical and operational leadership

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

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

All providers must also ensure all staff involved in local vaccination services are aware of escalation processes for clinical incidents and enquiries, which can be found on our website including reporting suspected side effects to medicines, vaccines or medical device and diagnostic adverse incidents used in coronavirus treatment to the MHRA to ensure safe and effective use via the Coronavirus Yellow Card reporting site.

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Safe and secure handling and management of COVID-19 vaccines

COVID-19 vaccines will have very specific handling requirements which are a condition of temporary authorisation under Regulation 174 of the Human Medicines Regulations 2012.

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

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

Vaccines that have not been transported or stored correctly may be ineffective or harmful; they would therefore no longer be within the conditions of their temporary authorisation and must not be used. The Lead Responsible CCG Chief Pharmacist will support GPs by ensuring safe handling and use of vaccines at PCN designated sites. Vaccines must be transported only in approved and validated cool boxes, and the temperature of the cool box and contents must be monitored and reviewed before use. Means of detecting when a temperature excursion has occurred are required and that any 'out of specification' recordings are addressed promptly and appropriately, and that a full audit trail is maintained.

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

The provider must ensure that appropriate and formal authorisation for vaccine supply, preparation and administration is in place. Patient Specific Direction (PSD) for Oxford/AstraZeneca, Patient Group Direction (PGD) for Pfizer/BioTech and Oxford/AstraZeneca, or the National Protocol for Pfizer/BioTech and Oxford/AstraZeneca can be used for these purposes, although the details and

requirements of each differ. A summary of the different legal mechanisms of administration are here. Additional PGDs, PSDs and National Protocol documents will be published in relation to each vaccine that becomes available. The staff groups who supply, prepare, and administer the COVID-19 vaccine must be those defined as eligible to do so, and must be competent to perform the tasks they are asked to carry out.

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

2.2 Workforce

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

Providers are responsible for ensuring that any staff involved in vaccinations are appropriately trained and the appropriate documentation is place for indemnity purposes i.e. honorary contract/staff sharing arrangement. Further information regarding the indemnity arrangements that apply for COVID-19 vaccination services can be accessed on NHS Resolution website.

We've provided some further advice on workforce planning in Appendix A.

2.3 Site preparation

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

Access

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

This includes having access to translation and interpretation services as required to support consent, mental capacity and clinical assessments. It may be helpful to have supporting literature available in a range of languages and easy read formats appropriate to the population being served. Contact your commissioner for information about local translation and interpretation services.

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

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

COVID-secure, social distancing and patient flow

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

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

- Use clear signage to direct patients to the appropriate site/space on arrival.
- Ensure alcohol gel/handwashing facilities are readily available for patients and staff, including at site entrances.
- Where possible, configure sites to support linear patient flows and have separate entrances and exits. This will be particularly helpful for enabling higher flow rates.
- De-clutter communal spaces and clinical rooms to assist decontamination.
- Communal areas should allow for physical distancing between patients; consider the use of floor markings, seating arrangements, signage and

queue marshalling to support this. This should apply for patients at all stages of the operating model.

- Ensure rooms or suitably private spaces are available to complete consent/capability and clinical assessments and vaccine delivery to enable patient confidentiality and privacy.
- Ensure there is sufficient fridge capacity for vaccines, that the area is secure and there is an area suitable for vaccine preparation.
- Ensure there is sufficient secure storage space for the vaccine consumables and waste generated by the local vaccination service.
- Consider measures such as asking patients to wait in private vehicles or designated external waiting areas, where possible, to reduce numbers in communal spaces during busy periods.
- Staff should wear the appropriate PPE, and pay attention to social distancing with each other.

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

Site security

Providers must follow any usual requirements set out by Care Quality Commission (CQC) and other relevant professional regulators, for securing all aspects of the designated sites, and any conditions of Marketing Authorisation for the vaccine.

Providers should liaise with their commissioners, local resilience forums and the police to put into place any reasonable security requirements for the local vaccination services and to ensure the police are aware of the location. You should consider site security (including staff, locks and alarms) if storing vaccine overnight, particularly in non-NHS sites. Providers should raise any issues or incidents with their commissioner and Regional Vaccination Operations Centre (RVOC); more information can be found on our website.

IT equipment and systems

Prior to starting vaccination, providers should have tested I.T. equipment and ensure relevant staff have received training and can access from the site the

different clinical and non-clinical systems relevant to COVID-19 vaccination. These include:

- National Booking System (not applicable to GP practice providers who will utilise local collaborative booking systems for designated sites).
- Pinnacle Point of Care System for recording the vaccination event.
- NHS Business Services Authority Manage Your Service tool to support the payment of the Item of Service COVID-19 vaccination fee to providers.
- Any reporting systems as directed by the commissioner for site readiness assessment and vaccine re-ordering.

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

IT services helpdesk vaccineservicedesk@england.nhs.uk / 0300 200 1000

2.4 First aid and resuscitation preparation

Providers should reasonably anticipate three medical emergencies associated with vaccination: Fainting, Hyperventilation, and Anaphylaxis.

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

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

- Location (Remoteness)

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

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

Anaphylaxis and Pfizer/BioNTech vaccine

An MHRA protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever the Pfizer/BioNTech vaccine is given. Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml adrenaline), with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis. Vaccine recipients should be monitored for 15 minutes after vaccination, with a longer observation period when indicated after clinical assessment. More information is available in this MHRA statement.

Additional update relating to contraindication and precautions for Pfizer/BioNTech vaccine is available in this MHRA statement and section 4.1

Additional requirements may also be needed when future vaccines, including the Oxford/AstraZeneca, are available. These will be notified to providers by service commissioners.

2.5 Occupational health requirements

Providers should ensure they have a local needlestick injury protocol accessible (ideally displayed) on site which should include contact details for their occupational health service and that staff understand what to do should they experience a needle stick injury. If you do not know who your occupational health services provider is, contact your local commissioner. The provider is responsible for ensuring a

nominated individual on site has knowledge and understanding of local needlestick protocols and ensure that they are followed.

2.6 Infection prevention and control (IPC)

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

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

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

3. COVID-19 vaccines and the Supply Inventory List

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

3.1 COVID-19 vaccines

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

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

Regulatory approval information specific to the Oxford/AstraZeneca vaccine can be found here; our 7 January letter also provides advice on the movement of the Oxford/AstraZeneca vaccine for roving vaccinations and between vaccination sites.

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

Pfizer/BioTech vaccine doses per vial

Health care professionals must always use the correct volume of diluent, and after dilution must aim to secure five full 0.3ml doses of this Pfizer/BioNTech COVID-19 vaccine in line with the manufacturer's instructions and as outlined in the Information for Healthcare Professionals.

After that has been done, there may be potential for a sixth full dose with some vials due to variances in fill volume and the syringe /needle hold up volume combinations used. This should be subject to health care professional judgement on a case by case basis. The manufacturer has stressed care should be taken to ensure a full

0.3 mL dose will be administered to the patient from the same vial. Where a full 0.3 mL dose cannot be extracted the contents should be discarded.

Oxford/AstraZeneca vaccine

The Oxford/AstraZeneca vaccine is supplied in packs of 10 vials. Each vial contains 8 or 10 doses of the vaccine. The unopened multi dose vial can be stored in the fridge (stored at 2- 8^{O}C) with a shelf life of 6 months. The vials should not be allowed to freeze and be protected from light. Once opened the vaccine should be used as soon as possible and within 6 hours. The vaccine may be stored between 2 ^{O}C and 25 ^{O}C during in use period. Each vaccine dose of 0.5ml is withdrawn into a syringe to be administered intramuscularly. It is normal for liquid to remain in the vial after withdrawing the final dose. The vaccine does not contain any preservatives.

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

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

Staff training for local vaccination services

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

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

Product-specific training will be made available as vaccines come on stream.

3.2 Supply Inventory List

The Supply Inventory List (SIL) is a 'free of charge' generic equipment and consumables list, which provides what is needed to effectively administer vaccinations. The volume of consumables has been proportioned to the number of vaccines and will be replenished with each vaccine order; Designated sites are not required to order items on the SIL; It will be a 'push' model.

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

If sites require additional items not on the centrally supplied lists, they should discuss this with their commissioner who may be able to provide the items or reimburse reasonable costs associated with site set-up from centrally provided funding the costs of the provider purchasing the items.

3.3 Waste management

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

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

- All PPE (e.g. facemasks) and soiled dressings (non-infectious) used during vaccinations should be disposed of as offensive waste and placed into the tiger bags; this should then be placed into the usual offensive waste stream of that setting.
- All hazardous waste should be disposed as clinical waste, including sharps disposed into the yellow sharps' bins and medicinal waste (e.g. vaccine vials as per any specific vaccine guidance) disposed int the yellow medicine waste container. The commissioner will advise designated sites how this waste will be collected which may be via the sites existing arrangements or via an alternate arrangement.
- Any dry ice used for storage and transport of vaccines should be placed in a secure well-ventilated area at room temperature, and allowed to sublimate away. Dry ice must not be disposed of through other waste containers or down sinks/toilets or outside drains.

4. Operating model

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

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

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

4.1 Identifying eligible patient cohorts

The Joint Committee on Vaccination and Immunisation has updated advice on prioritisation of patient groups, which can be found here.

Providers are responsible for using existing local patient systems to identify eligible patient cohorts based on age or risk status and prioritising as required. This may include identifying newly eligible at-risk patients. Providers should follow guidance from the commissioner on phasing access to different patient groups. Our 7 January letter and operational guidance provides information on vaccinating eligible health and social care staff.

Patients who are ineligible for COVID-19 vaccination

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

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

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

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

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

Pregnancy and breast-feeding

- JCVI does not advise that there is a requirement for routine pregnancy testing.
- Women who are trying to become pregnant do not need to avoid pregnancy after vaccination.
- JCVI advises that, for women who are offered vaccination with the Pfizer/BioNTech or Oxford/AstraZeneca COVID-19 vaccines, vaccination in pregnancy should be considered where the risk of exposure to Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV2) infection is high and cannot be avoided, or where the woman has underlying conditions that put them at very high risk of serious complications of COVID-19. In these circumstances, clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnant women.
- JCVI has advised that there is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with the Pfizer/BioNTech or Oxford/AstraZeneca COVID-19 vaccines.

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

Medical history: contraindications and precautions

- For all patient groups, those whose medical history contains absolute contraindications found within the vaccine's Summary of Produce Characteristics (SPC) will be excluded from using that particular vaccine and consideration given as to whether other vaccines may be offered at a different time.

- A very small number of individuals have experienced anaphylaxis when vaccinated with the Pfizer BioNTech COVID-19 vaccine. Following close surveillance of the initial roll-out, the MHRA has advised that individuals with a history of anaphylaxis to food, an identified drug or vaccine, or an insect sting can receive any COVID-19 vaccine, as long as they are not known to be allergic to any component (excipient) of the vaccine. All recipients of the Covid-19 vaccine should kept for observation and monitored for a minimum of 15 minutes. Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8).
- The British Society for Allergy and Clinical Immunology (BSACI) has advised that:
  - individuals with a history of immediate onset-anaphylaxis to multiple classes of drugs or an unexplained anaphylaxis should not be vaccinated with the Pfizer BioNTech vaccine. The AstraZeneca vaccine can be used as an alternative (if not otherwise contraindicated)
  - individuals with a localised urticarial (itchy) skin reaction (without systemic symptoms) to the first dose of a COVID-19 vaccine should receive the second dose of vaccine with prolonged observation (30 minutes) in a setting with full resuscitation facilities (e.g. a hospital)
  - individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting
- Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

Other vaccinations

- For all patient groups, COVID-19 vaccines should not routinely be given if any other vaccination has been received within the last 7 days, as set out in the Green Book Chapter on COVID-19 vaccination. However, adjacent or co-administration can occur where this would cause delay or reduce access

to either influenza or COVID-19 vaccine for certain patient groups e.g. care homes, housebound patients and hard to reach or vulnerable groups.

COVID-19 symptoms

- For all patient groups, COVID-19 vaccines should not be given if to anyone who are suspected or confirmed to have COVID-19 or are awaiting a test result.
- Patients are eligible for a vaccine following sufficient time after symptoms have stopped and the patient has recovered from COVID-19.

4.2 Dosage schedule

For both Pfizer/BioNTech and Oxford/AstraZeneca vaccines, a two-dose schedule is advised.

The second dose of the Pfizer/BioNTech vaccine may be given between 3 to 12 weeks following the first dose. The second dose of the Oxford/AstraZeneca vaccine may be given between 4 to 12 weeks following the first dose.

Following a review of clinical evidence and latest public health data, the JCVI and the Department of Health and Social Care has published updated guidance for the NHS on the prioritisation of first doses of COVID-19 Vaccines. The revised guidance recommends that as many people on JCVI priority list possible should sequentially be offered a first vaccine dose as the initial priority. This will protect the greatest number of at risk people overall in the shortest possible time and will have the greatest impact in reducing mortality, severe disease and hospitalisation.

Operationally this will mean that the second dose of both vaccines will be administered towards the end of the recommended vaccine dosing schedule of 12 weeks with most booked in the last week of the 12 week period.

Communications material to support the rescheduling of appointments can be found on FutureNHS.

4.3 Booking and communications

General practice providers are responsible under the Enhanced Service for using existing local systems to undertake local call and recall using nationally determined

text (available on FutureNHS), identifying and inviting all eligible patient cohorts on their registered list to book vaccination appointments.

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

Unregistered patients who are eligible for vaccination, and who request a vaccination from a PCN site should be assessed for eligibility and vaccinated. They should not be turned away or signposted elsewhere.

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

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

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

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

4.4 Arrival and check-in

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

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

- the patient is scheduled for a vaccination by checking their name and address against the booking system records; and
- the patient (when asked) confirms that they do not have any symptoms of COVID-19 (as per case definition), or are not awaiting the results of a COVID-19 test.

4.5 Consent and mental capacity

Consent

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

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

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

There is no legal requirement for consent to immunisation to be in writing and a signature on a consent form is not conclusive proof that consent has been given,

but serves to record the decision and the discussions that have taken place with the patient or in relevant cases, the person giving consent on a child's behalf.

The giving and obtaining of consent is viewed as a process, not a one-off event. Consent should still be sought on the occasion of each immunisation visit. Consent must be given voluntarily and freely.

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

Consent remains valid unless the individual who gave it withdraws it. If there is new information between the time consent was given and when the immunisation is offered, it may be necessary to inform the patient and for them to re-confirm their consent.

Patients who lack the relevant mental capacity

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

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

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

Where it has been established that the person lacks capacity to consent, a best interests decision should be taken in line with best interest checklist in section 4 of the MCA. This means that the decision-maker must consider all the relevant

circumstances, including the person's wishes, beliefs and values, the views of their family where appropriate and what the person would have wanted if they had the capacity to make the decision themselves. Care home staff or other types of carers should plan in advance to ensure that the health care professional administering the vaccine has the information they need to make an appropriate best interests decision about consent, at the right time.

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

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

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

Consent (given by a deputy or attorney with relevant authority in the person's best interests), or a best interests decision by a health care professional to vaccinate, or not, (informed by advance consideration and information gathering undertaken by carers), should be recorded. This is a required field on the Pinnacle Point of Care system. Where the person giving consent is not the patient (e.g. is their deputy or attorney etc) the name of that person and their relationship to the patient should also be recorded.

Additional considerations for care homes and care staff

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

Health and social care staff

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

4.6 Clinical review

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

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

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

4.7 Delivery of vaccination

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

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

4.8 Post-vaccination observation

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

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

For the Oxford/AstraZeneca there is not a requirement for 15 minutes observation unless this is indicated after clinical assessment.

As syncope (fainting) can occur following vaccination, all patients receiving a vaccination should either be driven by someone else or should not drive for 15

minutes after vaccination, nor should the individual operate machinery. This is in accordance with as per PHE vaccination guidance for healthcare practitioners.

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

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

4.9 Records management

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

The minimum data capture process will be:

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

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

3. Capture of the vaccination event details through;

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

5. Appendices

Appendix A: Workforce planning

There is a workforce support offer available to all COVID-19 vaccination centres. Each Integrated Care System (ICS) has a designated Workforce Lead Employer which will act as an operational workforce hub for the all vaccination providers in the local area. They can provide both health care professionals for employment such as returners to professional lists and volunteers such as St John's Ambulance staff.

The Lead Employer will work with all providers on workforce communications, management of rostering systems for volunteers and National Workforce suppliers and will have oversight of mandatory and statutory training of these staff. A list of the Workforce Lead Providers for each IC area is available on FutureNHS.

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

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

Workforce skill-mix

The table below presents some suggestions on how designated sites could utilise their workforce to support the delivery of local vaccination services. It may be appropriate to combine these roles across a smaller number of staff when providing local vaccination services to some sites e.g. care homes.

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

Appendix B: Health inequalities and inclusion health

The Joint Committee on Vaccination and Immunisation have provided as Annex A to their Priority groups for coronavirus (COVID-19) vaccination guidance, advice on COVID-19 vaccinations and health inequalities.

COVID-19 has had a disproportionate effect on certain sections of the population – including older people, men, people living in deprived areas, BAME groups, those who are obese and those who have other long-term health conditions, mirroring and reinforcing existing health inequalities, as highlighted in the PHE review of disparities in risks and outcomes and the PHE report on the impact of COVID-19 on BAME groups. Furthermore, the long-term economic impact of the pandemic is likely to further exacerbate health inequalities. Within the priority groups set by JCVI, designated sites will need to consider what reasonable steps they take to target uptake and should collaborate with their commissioner, local voluntary and community organisations to make sure those who are most excluded have access to local vaccination services.

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

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

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

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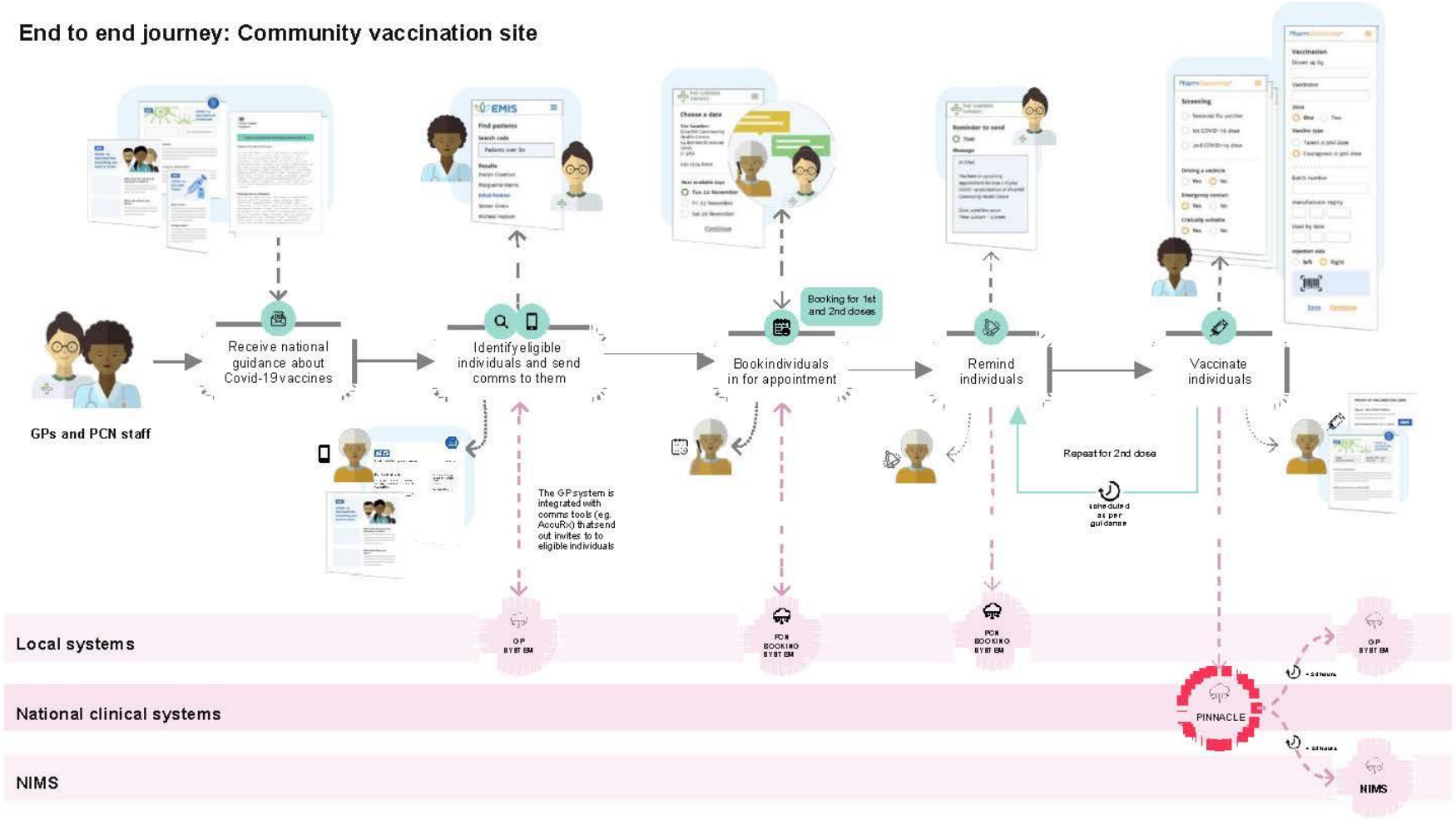
Appendix C: Visual end to end journey for local vaccination services (PCNs)



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

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

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

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

- Dose 1- all (or most) residents and staff on site
- Second visit- 1 week later to capture staff or residents who were unavailable on the day
- Dose 2- scheduled for the period of time specified by the vaccine manufacturer
- Fourth visit- to capture outstanding doses one week later.

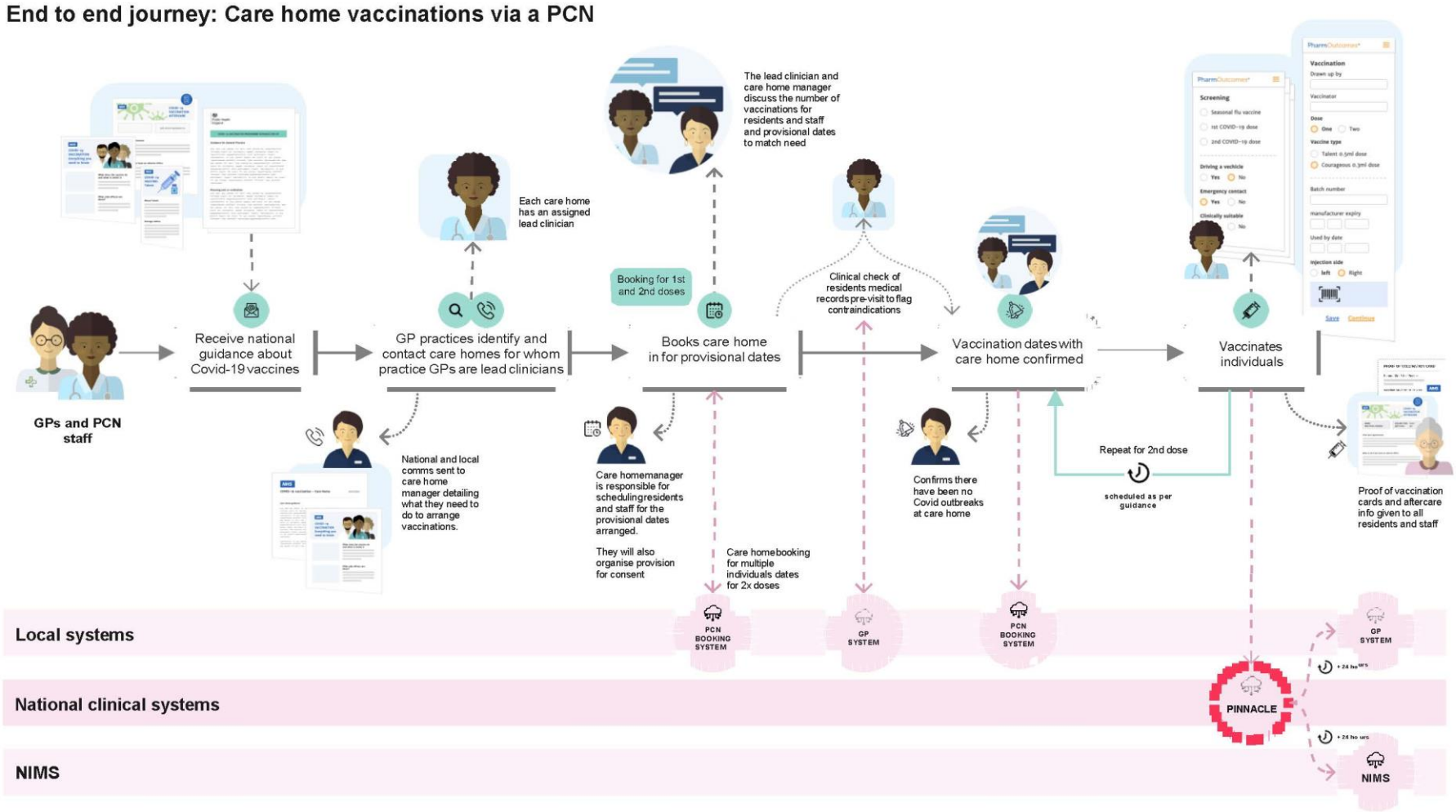
A regular follow up visit until mass population coverage has been achieved may be required, providers should agree an ongoing rolling process with care homes.

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

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

Version 3.2, 14 January 2021

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



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Checklist for Care home vaccinations operating model

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

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

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

Care home engagement

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

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

Site configuration

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

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

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

Influenza vaccine at care homes

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

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

Guidance for COVID-19 vaccination in care homes that have cases and outbreaks

COVID vaccine should be offered to older adults in care homes and their carers, with the aim of achieving high uptake as rapidly as possible. This includes when other residents have been diagnosed as having COVID-19 infection. A number of factors will need to be considered before an immunisation team attends a care home. It is recommended that a risk assessment is carried out by the lead vaccinator and that this is performed in conjunction with the care home manager. If needed, advice should be sought from others such as the local health protection team, CCG infection prevention and control lead and local Director of Public Health. Further guidance is available here

Vaccination team

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

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

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

Training

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

Vaccine provision for care homes

PCNs may access Pfizer/BioTech vaccines for use in care homes as follows:

- 75-dose pack(s) available for order and can be used for large care homes
- 5-dose vial(s) extracted from 975-dose vaccine pack(s) ordered primarily for PCN site-based vaccinations, which can be used for smaller and medium sized care homes.

PCNs may access Oxford/AstraZeneca vaccine for use in small care homes and housebound patients.

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

COVID-19 testing programme

Providers should ensure PCN staff testing is in place and all members of the vaccination team should take a PCR / LFT test prior to visiting care homes to mitigate risk of PCN staff testing positive on arrival (which could have implications for the whole vaccination team leading to disruption of the planned session and potential vaccine waste).

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

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

Consent and mental capacity for care home residents

Consent grouping

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

- Those who are likely to have mental capacity to consent

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

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

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

Consent discussions

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

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

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

Consent assurance

Health care professionals administering the vaccine will be best placed to assess if the resident has relevant mental capacity to consent to the vaccination themselves, and if they do not, take the final best interests decision, on behalf of the person, whether or not to vaccinate (unless there is an attorney or deputy with relevant authority). They will be trained to discharge these duties under the Mental Capacity Act 2005.

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

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

Information about COVID-19 vaccines

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

Clinical review

The PCN clinical lead / clinicians should review medical records of each resident for allergies, whether medically fit or have any other exclusions for why they shouldn't receive a vaccination. More information can be found in section 4.5 of this SOP.

PCNs may need to allocate a number of staff for clinical review across GP practices within the PCN grouping to ensure all residents patient records can be accessed.

EHCH clinical leads should also be consulted to consider any other useful clinical information about residents within the care home.

Care home staff vaccinations and reserve list

Both care home staff and residents are eligible for a vaccination as they are in priority group 1 and therefore care home staff should be scheduled for vaccinations as well as residents. PCNs should encourage care home providers to consider how to maximise staff uptake of the vaccination through targeted conversations by line managers and with teams, using the staff and public communications materials. Conversations should also consider any employer support to access vaccination via other sites (such as travel time or mileage) for staff not present onsite for scheduled visits.

Deployment of the vaccine may require the majority of/all staff who are not vaccinated on site to receive vaccination via alternate delivery routes and sites, subject to the vaccine characteristics and JCVI recommendations. Care home staff will be able to access vaccinations at the designated site(s) of the PCN grouping leading the vaccination of the Care Home where they work, via their own registered GP practice (if in a different PCN grouping), a mass vaccination site or any other local provider offering vaccination e.g. Community Pharmacy.

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

Reserve Lists

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

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

Cold chain management

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

Cold chain preparation

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

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

Cold chain training

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

Cold chain validation

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

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

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

- Load pattern
  - Ice or chilled blocks (including chill method to ensure fully chilled)

  - Positioning in the cool box
  - Type of cool box
  - Number of vaccine vials in the cool box
- Journey/storage time
- Maximum ambient temperature
- Number of times cool box is opened during use, and duration of opening

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

Validation cannot be extrapolated between different types of cool boxes.

Vaccine cold chain properties

Pfizer/BioNTech:

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

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

Oxford/AstraZeneca:

Distribution as a part of deployment can be controlled at 2-8 ^{O}C throughout its shelf life of 6 months. The vaccine must not be allowed to freeze and be protected from light.

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

Once a vial is opened use as soon as practically possible and within 6 hours. The vaccine maybe stored between 2 ^{O}C and 25 ^{O}C during the in-use period. More information on movement of this vaccine can be found in our 7 January letter.

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Visual end to end journey of cold chain

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

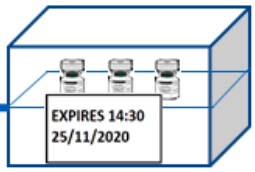
Cool boxes must be suitable for the duration of use. They must be prepared according to the manufacturer's instructions.

Position the cool box as close as possible to the fridge

Select and pack the required number of thawed vials

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

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

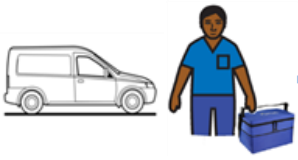


The vials must be securely held in an upright position to minimise movement in transit, and should be protected from light.

Pack the new vial container into cool box

The cool box packing pattern should follow the manufacturer's instructions.
- minimise movement or agitation of the vials
- frozen ice packs must not come into direct contact with the vaccine.

Transport to the end user location



Transit time - MHRA Conditions of Authorisation must be followed:

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

Oxford/AstraZeneca:
- Multiple journeys permitted; once vial is punctured, use within 6 hours

Vaccine transport container

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

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

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

If PCNs are transporting a Pfizer 75-dose pack then a vaccine transport container may not be required, but PCNs need to still ensure the pack is secured for transport and has no direct contact with gel packs.

Post vaccine observation and adverse reactions

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

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

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

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

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

PCNs will need to consider consulting the community teams for local knowledge, and on how they can offer local vaccination services to patients living in the community who usually receive treatments at home and are generally classed as housebound.

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

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

However there are infection prevention and control considerations:

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

- As standard practice for this vaccine, swab the vial septum with an alcohol swab prior to every dose withdrawn and leave to dry for 30 seconds.

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

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

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

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

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

Post vaccine observation and adverse reactions: Further information on post vaccine observation and record keeping can be found in section 4.7 and 4.8 of this SOP. The roving vaccination team should record in Pinnacle during the visit, the patients should be given a post vaccination record card with details of their vaccination and informed that they will be contacted about the second dose.

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