

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.

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.

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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 PCN sites was set out in our [7 December letter](#). This section should be read in conjunction with the 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. daily 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](#).

Safe and secure handling and management of COVID-19 vaccines

Some types of COVID-19 vaccination have very specific handling requirements which are a condition of their Regulation 174 approval under the Human Medicines Regulations 2012.

The characteristics of the different vaccines may vary considerably and will increase in clarity over time. Prior to licensing the product characteristics are available in the relevant 'Healthcare Professional Factsheet' and patient information in the 'Consumer Factsheet'. Following award of the Marketing Authorisation for the vaccine, this information is available in the Summary of Product Characteristics and Patient Information leaflet respectively.

Some vaccines are inherently unstable at higher temperatures or when agitated so maintaining the correct cold chain will be critical for all vaccines.

Vaccines that have not been transported or stored correctly may be ineffective or harmful; they would therefore no longer be within the terms of their product authorisation and must not be used. Vaccines must be transported only in approved and validated packaging, and the temperature of the vaccine carrier and contents are 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 vaccine and medicines are in place in accordance with principles and guidance encompassed in the Royal Pharmaceutical Society of Great Britain [Professional guidance on the safe and secure handling of medicines](#).

The provider must ensure that appropriate and formal authorisation for vaccine administration is in place such as a Patient Group Direction, protocol or written instruction, and that the staff groups who are supplied with, prepare, and administer the COVID-19 vaccine are those defined as eligible to do so. Our [8 December letter from the Chief Pharmaceutical Officer](#) sets out information on governance, handling, and preparation of vaccines by PCN-led local vaccination services.

Under a Patient Specific Direction (PSD), the prescriber is legally accountable for the safe and secure handling and management of COVID-19 vaccines at the designated site(s), under [The Human Medicines Regulations \(2012\) Regulation 3](#).

Healthcare professionals working under a Patient Group Direction (PGD) and anyone clinically supervising administration of the vaccines under a National

Protocol also have legal accountability for ensuring the safe and secure handling requirements are met.

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 contact the relevant Specialist Pharmacy Services [Regional Quality Assurance Specialist](#) 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](#).

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.

2.4 First aid & 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](https://www.gov.uk).

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 the [anaphylaxis algorithm chart](#) and the [resuscitation of adult COVID-19 patients primary care setting infographic](#) may be helpful.

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](#).

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

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 will be published on the [Specialist Pharmacy Service](#) once available.

Regulatory approval information specific to the Pfizer/BioTech vaccine can be found [here](#).

Further information on the vaccine supply process for PCN sites can be found in our [7 December letter](#).

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 into 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 a fixed site (i.e. NHS or non-NHS site), or local vaccination services are attending a site where patients are based (e.g. care home, roving vaccinators).

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 provided 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.

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](#)

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 (Pfizer/BioNTech vaccine)

- For women of childbearing age, the possibility of pregnancy should be excluded before vaccination, for example by checking whether a pregnancy test is required
- Women should be advised to avoid pregnancy for at least 2 months after their second dose.
- For women who are breast-feeding, they should be excluded from vaccinations.

Further information can be found on the [GOV.uk website](#).

Medical history contains contraindications

- For all patient groups, those whose medical history contains absolute contraindications found within the vaccine's [Summary of Product Characteristics \(SPC\)](#) will be excluded from using that particular vaccine and consideration given as to whether other vaccines may be offered at a different time.
- For all patient groups, those with a history of immediate-onset anaphylaxis to a vaccine, medicine or food should not receive the Pfizer/BioNTech vaccine. A second dose of the Pfizer/BioNTech vaccine should not be given to those who have experienced anaphylaxis to the first dose of Pfizer/BioNTech vaccination; more information on this can be found in this [MHRA statement](#).

Other vaccinations

- For all patient groups, COVID-19 vaccines should not be given if any other vaccination (e.g. influenza) has been received within the last 7 days

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 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 (where available), 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 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.

Unregistered patients who are eligible for vaccination but have received national and local call and re-call communications, 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.
- 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](#).

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.

4.3 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.

4.4 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, or 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. 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 the person giving consent on a child's behalf.

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.

Patients who may lack 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 principles of best interests decision making under the MCA are 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 health care professional can only give the vaccination if the deputy or attorney has first given their consent.

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), or a best interests decision 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.

Additional considerations for care homes and care staff

Care homes should be encouraged to seek consent in advance of local vaccination services attending these sites, as further actions may be required to ensure informed consent can be sought or the appropriate person with legal authority to give consent can be identified in advance.

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](#).

4.5 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.

4.6 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](#).

4.7 Post-vaccination observation

Post-observations periods should follow normal arrangements for observation after vaccination and pharmacovigilance, as set out in the Green Book. For the Pfizer/BioNTech 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](#).

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, 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 and next appointment if applicable (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 here](#)).

4.8 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

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 and highlights the time taken to vaccinate 100 people based on differing numbers of vaccinators and time between vaccinations; note the live-play exercise carried out to simulate the large scale vaccination sites observed a timing point of approximately 8 minutes to vaccinate each patient (excluding any post-vaccination observation where required).

	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](#).

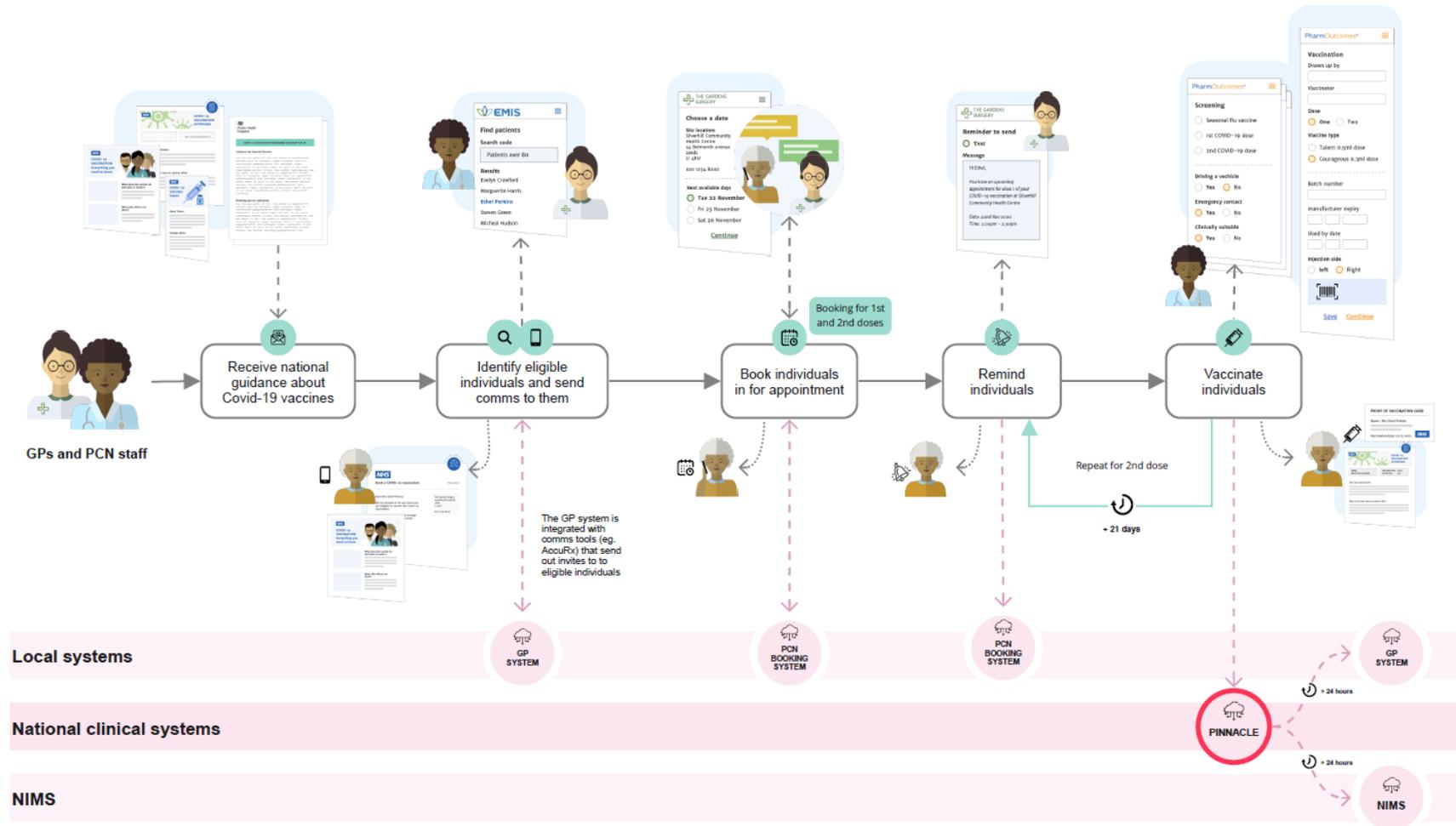
COVID-19 has had a disproportionate effect on certain sections of the population – including older people, men, people living in deprived areas, BAME groups, those who are obese and those who have other long-term health conditions, mirroring and reinforcing existing health inequalities, as highlighted 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.

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



Appendix D: Additional considerations for providing local vaccination services for care homes

Scheduling of vaccinations for care home residents and staff (subject to vaccine being approved for deployment in care homes)

The PCN should consider whether a mobile/roving vaccination team can deliver the required service, and what assistance other providers such as Community/District nursing teams could support vaccination to this patient cohort. 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.

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, PCN's should agree an ongoing rolling process with care homes.

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.

Care home providers 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. The registered GP Practice would normally be the first contact for advice around adverse reaction. The PCN 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

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.

On 4 December, the Minister for Social Care [wrote to all care providers](#) Local Authority Chief Executives and Directors of Adult Social Care advising them on what to expect in relation to the vaccination of residents and staff. The letter set out the actions providers and care homes managers could take in supporting NHS providers to deliver vaccinations.

Mental capacity and consent for care home residents and staff

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).

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.

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 care home or other carers 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). 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](#).

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.

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.

Other considerations for PCNs visiting care homes

- Vaccination teams should consider being tested prior to visiting care homes to mitigate risk of vaccinators testing positive on arrival (which could have implications for the whole vaccination team leading to disruption of the planned session and potential vaccine waste).
- PCNs and roving vaccination teams should consider whether staff need to be tested or had a recent test) in advance of attending care homes.
- Ensure vaccination event is reported back to their patient record and include any post-vaccination issues experienced.
- EHCH clinical leads should enable consistency and share good practice and iterate process as needed.

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

