

Letter on urgent preparing for community pharmacy to contribute to a potential COVID-19 vaccination programme

ANNEX A: Indicative Local Enhanced Service Agreement: COVID-19 Vaccination Programme 2020/21

Reference Guide

27 November 2020

Several potential vaccines for COVID-19 are in the later stages of phase III trials. If one or more are authorised for use, the NHS needs to be ready to start immediate vaccination.

NHS England and NHS Improvement propose to commission a COVID-19 vaccination service from selected community pharmacies to complement the general practice COVID-19 vaccination enhanced service and other local vaccination services, provide additional flexibility and increase access as is required. This will be commissioned as a Local Enhanced Service by NHS England and NHS Improvement regional teams in consultation with Local Pharmaceutical Committees.

An indicative LES agreement will be published shortly. This table indicates the likely content of the indicative LES agreement to support pharmacy contractors to start planning. It should be read in conjunction with guidance on the “**Community Pharmacy Site Designation Process: Covid-19 vaccination programme 2020/21**”.

	FAQs	Planning assumptions
1	Eligible cohorts	
1.1	Which cohorts are included in the community pharmacy LES agreement?	<p>Aspects of a potential COVID-19 vaccination programme will be finalised when final trial results and licensing has occurred. The Joint Committee on Vaccination and Immunisation (JCVI) will then finalise cohort prioritisation, and identify which vaccines are most suitable for different cohorts. The JCVI has already set out a draft prioritisation and order in which eligible adult cohorts should be vaccinated.</p> <p>Community pharmacy will have an important role to play in contributing to administering vaccinations to ‘at risk’ patients and health and social care staff. Pharmacy contractors who are commissioned to provide the service will need to align vaccination delivery with the national timetable for the call/recall of eligible cohorts where appropriate.</p> <p>For cohorts subject to national call/recall, once patients are notified by the national call/recall service that they are eligible for a vaccination, they would have the choice to book an appointment at the general practice-led vaccination centre appropriate to their GP registration or use the National Booking Service to be vaccinated by another provider such as a community pharmacy or mass vaccination clinic.</p>
1.2	Will eligible patients be able to choose where they are vaccinated?	<p>Subject to available vaccine supply and appointment capacity, most patients will be able to choose where they are vaccinated. Appointments for community pharmacy providers will be booked through the National Booking Service, where a choice of providers based on patient location will be given.</p> <p>Both doses of the same COVID-19 vaccination must be administered by the same provider / designated site (unless there are exceptional circumstances which will be listed in the service agreement).</p>

1.3	Can patients choose to be vaccinated at a pharmacy that is not their usual pharmacy?	<p>Community pharmacy will have an important role to play in contributing to administering vaccinations to 'at risk' patients and health and social care staff.</p> <p>Once patients in these cohorts are notified that they are eligible for a vaccination, they will have the choice to book an appointment at their local/registered general practice-led vaccination site covering the PCN area or to book an appointment with another provider.</p>
1.4	When will different patient cohorts come on stream?	<p>JCVI is expected to confirm shortly the list of cohorts and prioritisation order. A national announcement will be made when cohorts come on stream.</p>
1.5	What are the eligibility criteria for high and moderate risk patients?	<p>The eligibility criteria will be confirmed by JCVI in due course</p>
1.6	Will community pharmacies be able to vaccinate their own staff?	<p>Once eligible for a COVID-19 vaccination, community pharmacy staff will be eligible for vaccination under the LES and able to choose to be vaccinated at a designated site of their choice.</p>
1.7	Who will vaccinate care home residents?	<p>Normally the responsibility for vaccinating patients in a care home will sit with the PCN and they should make arrangements to ensure these patients are vaccinated as appropriate. However, pharmacy contractors may enter into a subcontracting arrangement with their local PCN or be commissioned by their NHS England regional team to provide vaccination in care homes if this is necessary to deliver the vaccination programme. The aim is to keep visits to care homes to a minimum to reduce risk of transmission of COVID-19.</p>
1.8	Who will provide services for health inclusion groups, eg homeless people?	<p>Each PCN grouping is required to work with their local regional team to understand the current healthcare provision for vulnerable groups. Every local system should have a plan for full coverage for health inclusion groups and community pharmacy contractors may have a role to play in these plans in some areas through a sub-contacting arrangement with the lead provider or if directly commissioned by NHS England and NHS Improvement to meet a particular need locally.</p>

<p>1.9</p>	<p>Will informal and unpaid carers fall into the same cohort as care home workers?</p>	<p>JCVI is expected to confirm final cohorts and prioritisation soon.</p>
<p>1.10</p>	<p>Will community pharmacies be able to vaccinate housebound patients?</p>	<p>Yes, where the pharmacist has a DBS certificate, they can vaccinate housebound patients, however it is anticipated that many housebound patients will be vaccinated by other parts of the service. Contractors who do not wish to become a designated vaccination site may be able to help vaccinate house-bound patients should discuss whether there is a local need for a subcontracting arrangement with their local PCN or NHS England regional team. The aim is to minimise visits to house-bound patients.</p> <p>It is recognised that running a potential COVID-19 vaccination programme requires “all hands to the pump” and pragmatism. We encourage systems to maintain and develop local ways of maximising joint working between PCNs, community pharmacies and other community partners, making every contact count, eg in relation to housebound patients.</p>
<p>1.11</p>	<p>Is the vaccine for over 85-year olds?</p>	<p>JCVI will confirm cohort prioritisation soon. But the over 80s are currently expected to be an early cohort: https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-25-september-2020/jcvi-updated-interim-advice-on-priority-groups-for-covid-19-vaccination</p>

2	Collaboration	
2.1	Can all community pharmacies sign up to deliver the local enhanced service?	<p>All pharmacy contractors will have the opportunity to nominate themselves to participate in the LES but in doing so, they must be able to deliver all of the requirements. A key requirement is that the pharmacy can provide a local vaccination site that meets the core requirements for COVID-19 vaccination, which will be confirmed via the site designation process.</p> <p>Nominated sites that do not meet all of the designation criteria cannot be recommended for designation. Pharmacy contractors should note that even if a site is assessed by the regional team as having met all of the designation criteria, this does not automatically mean that it will be designated as further factors such as equity of access, geographical coverage and total number of sites that can be accommodated within the COVID-19 vaccination supply chain and available workforce need to be considered.</p>
2.2	Why is it a Local Enhanced Service rather than an Advanced Service?	<p>NHS England is the commissioner of vaccinations and immunisation services (under Section 7A of the NHS Act 2006). A national agreement will be provided centrally for consistency across the COVID-19 vaccination programme. However, because of the supply and logistics constraints commissioning will be on the basis of need and other practical considerations and commissioning under the terms of a LES allows designation of sites as needed by regions.</p>
2.3	Can the LES agreement be locally amended?	<p>No. As this is a nationally agreed service specification it is not possible for local commissioners to amend the LES agreement. Should any national amendments be required, NHS England and NHS Improvement would discuss these with PSNC and LPCs as appropriate.</p>
2.4	Does expressing an interest in becoming a site formally commit pharmacy contractors to sign up to deliver the LES?	<p>Expressing interest in becoming a designated site does not formally commit a pharmacy contractor to signing up to deliver the LES agreement. However, it is assumed that in expressing this interest the contractor has an intention to do so and so should not express interest on a speculative basis. Once designated sites have been confirmed, contractors will be offered the opportunity to sign up to deliver the LES, the terms of which become binding once sign up has taken place.</p>

2.5	When does the LES start?	The final LES agreement will be issued in December. Pharmacy contractors confirmed as a designated site will then be asked to sign up to the LES. The LES will come into effect once vaccinations become available.
2.6	How long will the LES be for?	We anticipate that it will be until the end of March 2021 initially, or until the COVID-19 vaccination programme comes to an end.
2.7	Will pharmacies be able to sign up to the LES after the initial opportunity in December 2020?	As the provision of the vaccination programme is across a variety of providers, the designation of local PCN sites and community pharmacies is intended to provide sufficient population coverage. It may therefore not be possible for pharmacies to join after the initial opportunity, if there is sufficient coverage for the local population.
2.8	Can pharmacies collaborate to deliver the LES?	<p>Pharmacy contractors who are commissioned to provide the LES from a designated site are responsible for meeting the terms of the LES agreement. Where appropriate, they may choose to subcontract with other providers.</p> <p>We are also commissioning an enhanced service from general practice. Community pharmacy contractors may alternatively wish to discuss collaboration with their local PCN and offer their support them through a sub-contracting arrangement to help deliver maximum vaccine uptake.</p>
2.9	What will be the notice period for a pharmacy to withdraw from the specification?	42 days to enable sufficient time for the recommissioning of services through other providers.
3 Designation process and timescales		
3.1	What is the designation process and criteria?	Please refer to guidance document entitled: Community Pharmacy Designation Process: COVID-19 vaccination programme 2020/21
3.2	Do designated sites need to be existing registered with the General Pharmaceutical Council?	It is likely that in many cases vaccinations would take place on a site other than the registered premises and that GPhC standards will apply to the provision of pharmaceutical services by the registered pharmacy.

3.3	Can pharmacy contractors use a drive-through model to vaccinate?	Drive through vaccination sites should not be the only designated site in an area, given the need for equity of access to those patients who do not have access to a car. However, a drive through site may be included as a designated site by the commissioner where it is not the sole option in an area and the model has been clinically assured.
4 Call and Recall / Appointment booking / Comms		
4.1	Will there be a national call /recall system?	Yes. Eligible patients will receive a letter from the national programme inviting them to book an appointment through the National Booking Service. The text will reflect that PCN groupings will also be writing out to eligible cohorts and that patients have a choice of provider. National call and recall will not apply to some of the earlier cohorts such as care home residents and health and social care workers.
4.2	What is the ask of pharmacies in supporting national call / re-call?	In addition to the national call/re-call service, pharmacies will be asked to support their patients who are within the eligible cohorts, by reminding them of the availability of the vaccine, benefits of vaccination, the process for booking an appointment, and the importance of completing the entire course of vaccinations.
4.3	How would vaccines be ordered by pharmacy contractors?	<p>There will be a strict system for ordering based on national allocations. The national programme will be engaging with designated sites soon after the sites are confirmed to start sharing information and establishing the supply chain.</p> <p>The national programme will seek to ensure that the principle of equivalence applies, and that pharmacy contractors will be given fair access to available vaccine supply.</p>
4.4	How will patients book appointments?	<p>Patients will be advised on how to book an appointment by the national call / recall service.</p> <p>Patients will be able to book an appointment with a community pharmacy provider through the National Booking Service, and pharmacies will need to comply with the additional</p>

		requirements involved, eg uploading clinic times to the system so that bookings can be made.
4.5	What advice and support will be made available to patients pre and post vaccinations?	This will be confirmed in due course, but Public Health England (PHE) is expected to produce pre and post vaccination materials that pharmacies will be able to use. This will include hard copies of post-vaccination information leaflets.
4.6	Is there any flexibility in the requirement to deliver the vaccinations 8am-8pm, seven days a week?	<p>As vaccines come into the country, we need to get them out at the pace at which they are becoming available with minimum wastage. It will be essential to have capacity in the system to deliver when it is appropriate to do so.</p> <p>Some potential COVID-19 vaccines require specific handling and so, if necessary, pharmacies will need to have the ability to deliver vaccinations between 8am and 8pm seven days a week to avoid any going to waste.</p>
4.7	Could pharmacies vaccinate on Saturdays and/or Sundays only if they could meet the required numbers e.g. 1000 doses per week?	<p>Designated sites are encouraged to deliver as many vaccinations as possible as quickly as possible subject to supply. However, pharmacies should also consider equity of access, mindful that for some patient's weekend appointments may be easier but for others this may not be the case.</p> <p>Potential COVID-19 vaccines require specific handling and so if necessary, designated sites are likely to need to have the ability to deliver vaccinations between 8am and 8pm seven days a week to avoid any going to waste.</p>
5	Preparation and administration of the vaccinations	
5.1	From which date will pharmacies be expected to deliver vaccinations to eligible cohorts?	<p>We will aim to give all sites at least 10 days' notice of the first vaccines becoming available to ensure sites can be stood-up and clinics arranged.</p> <p>In recognition of the valuable role that community pharmacy plays in both the flu vaccination service and the supply of medicines throughout December, we are planning for pharmacy-led sites to be ready to administer vaccines from late December or early January with exact date dependent on individual vaccine licensing dates and manufacturers' supply schedules.</p>

		When vaccines come on stream, pharmacy contractors will need to align vaccination delivery with any local call and recall arrangements and the national timetable for the call/recall of eligible cohorts. The ambition is to safely vaccinate the maximum number of patients in the minimum amount of time, across a range of vaccination centres, subject to vaccine supply and with minimum wastage.
5.3	What preparation of the vaccine is required?	<p>We will confirm this once the final vaccine characteristics have been confirmed. We anticipate Summaries of Product Characteristics (SPCs) will be published.</p> <p>Pharmacy contractors should plan on the assumption that vaccines will come in multi-dose vials and will need drawing up. Contractors should also assume that there may be additional requirements. This may include an expiry time based on when a multi-dose vial was punctured, meaning that the expiry time must be monitored and patients must be seen in relatively quick succession so as to reduce waste.</p>
5.4	What provision is there for 'drawing-up' time and coordination (not pre-filled syringes)	Pharmacy contractors should plan on the assumption that vaccines will come in multi-dose vials, will need drawing up and may require reconstitution. Contractors should also assume that there may be additional requirements, such as limits on time at ambient temperature and limits on time at 2-8°C before use.
5.5	What is the medium used for the vaccine e.g. gelatin?	This will be confirmed once we have further information. We anticipate Summaries of Product Characteristics (SPCs) will be published in due course.
5.6	What clinical guidance will be made available?	Online training materials will be made available. Standard Operating Procedures will be published, along with clinical guidance and legal authority such as Patient Group Direction or National Protocol.
5.7	Will there be a national PGD?	Yes, there is likely to be a national PGD and a National Protocol (subject to Ministerial approval) for using an expanded vaccinator workforce. These are being developed by PHE and will be authorised by NHS England and NHS Improvement for local use

<p>5.8</p>	<p>What PPE do staff need to wear?</p>	<p>The requirement is to follow the national guidance on Infection Prevention and Control for vaccinations in a vaccination site and when attending a patient in their home or care home.</p> <p>PPE will be supplied as part of the consumables drop to each site ahead of vaccine deliveries and pharmacy contractors do not need to source this via the DHSC portal which should be used for their COVID-related PPE supply to deliver their usual pharmaceutical services.</p>
<p>5.9</p>	<p>What observation period is required post vaccination? And who will observe the patients?</p>	<p>JCVI will confirm this in due course, but pharmacies should plan on the assumption that a 15 minute observation period in a socially distanced space will be required for some patients post vaccination. This may include where the patient would be driving a car from the vaccine site or based on the clinical judgement of the supervising health professional.</p>
<p>5.10</p>	<p>How many doses of the vaccines will be required?</p>	<p>Contractors should plan on the assumption that two doses of the <u>same</u> vaccine will need to be administered to each patient, 28 days apart. The spacing between vaccines is subject to confirmation from the JCVI and may be specific to the type of vaccine being administered.</p>
<p>5.11</p>	<p>How soon can a COVID-19 vaccination be administered after a flu vaccination?</p>	<p>This will be confirmed in due course, but contractors should plan on the assumption there needs to be at least 7 days between other vaccinations and COVID-19 vaccinations.</p>
<p>5.12</p>	<p>Do patients have to have the second dose at the same site as they had their first dose?</p>	<p>Unless there are exceptional circumstances which will be specified in the LES agreement, we would expect patients to have their second dose at the same site they had their first dose wherever possible</p>

6	Workforce	
6.1	Who can administer the job?	The Statutory Instrument ¹ allows the vaccine to be administered according to a National Protocol using registered healthcare professionals to carry out the clinical assessment, consent and preparation and suitably trained non-registered staff to administer the vaccine under clinical supervision by a registered healthcare professional. The Statutory Instrument does not specify who these non-registered vaccinators might be. This will be covered in the National Protocol which will be published soon (subject to Ministerial approval).
6.2	What are the training requirements for staff administering COVID-19 vaccines?	<p>All staff involved in administration of COVID-19 vaccines will need to complete the relevant on-line vaccine specific training and have the necessary skills and training to administer vaccines in general, including completion of the general immunisation training, for example that available on e-learning for health, and face-to-face administration training.</p> <p>Pharmacy contractors will be expected to oversee and keep a record to confirm that all staff have undertaken the training prior to participating in vaccinations.</p> <p>There will be a COVID-19 vaccination programme overview pack for all staff that can be used for onboarding.</p>
6.3	How would pharmacy contractors access COVID-19 vaccination training? How long will the training take?	National e-learning will be available on e-learning for healthcare – it is likely that most pharmacy staff already providing the flu vaccination service will only be required to undertake COVID-19 vaccine specific chapter(s) of the online training package. If and when any additional vaccines become available, a new chapter will be added to the e-learning materials for each new vaccine.
6.4	What additional workforce will be made available for pharmacies to draw down on?	<p>Pharmacies will need to provide the majority of the required staff from their own workforce, though additional workforce, including volunteers may be available through local channels.</p> <p>More detail will be shared on how pharmacies can access support from volunteers and additional workforce.</p>

¹ Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/uksi/2020/1125/pdfs/ukxi_20201125_en.pdf

		<p>A template honorary contract and template workforce sharing agreement will be developed.</p> <p>Our shared ambition is for access to pharmaceutical services to be maintained for all patients. Pharmacy-led designated sites may need to work with other community pharmacies to ensure that patients get both the vaccinations and pharmaceutical services that they need.</p> <p>Where contractors can demonstrate a clear plan to maintain pharmaceutical services, eg where two premises in a locality have agreed to work collaboratively, they may wish to apply to NHS England and NHS Improvement to change their hours or to limit the provision of pharmaceutical services from their premises for the purposes of administering COVID-19 vaccines.². Otherwise the pharmacy contractor will be expected to nominate alternative premises that can meet General Pharmaceutical Council standards and requirements outlined in the LES agreement.</p>
<p>6.5</p>	<p>Will stewards be available to support designated vaccination sites?</p>	<p>This will be down to the features of the individual site, local preference and requirements. Pharmacy contractors should use local relationships and resources where possible.</p> <p>Contractors will need to assess the need for security at their designated site and respond appropriately.</p>

² <https://www.legislation.gov.uk/uksi/2020/1126/made>

7	Funding	
7.1	<p>What is the Item of Service (IoS) fee?</p>	<p>The national programme will seek to ensure that the principle of equivalence applies between pharmacy and other providers, e.g. on funding, and that pharmacy contractors will be given fair access to available vaccine supply rather than this being determined by another provider.</p> <p>The Item of Service fee will be £12.58 per vaccination. This additional payment, beyond the flu vaccination IOS, recognises the extended requirements around the COVID-19 vaccination, including training, the need for post-vaccine observation and any associated costs thereafter.</p> <p>The Item of Service fee will be paid on completion of the final dose (ie £25.16 if the vaccination requires two doses) unless in exceptional circumstances the final dose cannot be administered, eg because of intolerance/clinical agreement.</p>
7.2	<p>What if pharmacies are unable to deliver the second dose of the vaccine for legitimate reasons? Would they be paid for the first vaccination?</p>	<p>Providers must make proactive attempts on at least two separate occasions to contact and recall patients who have had an initial dose but have not booked or have cancelled subsequent appointments. The date and times of attempted contacts must be recorded.</p> <p>An exceptions process will be in place if the completing dose is inappropriate, in which case a payment for a single dose will be made (£12.58). The service agreement will confirm the exception criteria, but this is likely to include:</p> <ul style="list-style-type: none"> (a) The vaccine is no longer suitable for the patient because: <ul style="list-style-type: none"> (i) Medicine intolerance or allergy was discovered during administration of the first dose; (ii) The patient has commenced end of life care before a second dose of the vaccine could be provided; (iii) The patient has died before a second dose could be provided. (b) The patient has chosen not to receive the second dose of the vaccine following a documented shared decision making conversation;

		<p>(c) The patient has moved residence and/or has declined to receive subsequent doses from the first provider;</p> <p>(d) The patient did not attend a booked appointment and the pharmacy contractor has attempted contact with the patient on at least two separate occasions within a week of the appointment; or</p> <p>(e) The other provider is no longer able to administer the completing dose, eg because they no longer have access to a designated site or a supply of vaccines.</p> <p>Pharmacy contractors must record the relevant qualifying criteria in accordance with the reporting requirements which will be published.</p>
<p>7.3</p>	<p>Will there be any sources of funding available in addition to the IoS fee?</p>	<p>NHS England and NHS Improvement has provided additional support to pharmacy contractors to support the flu programme (eg additional venue hire). These arrangements will be extended to support the COVID-19 vaccination programme, which will also be supported by a national inventory to supply vaccines and consumables, and limited funding for pre-agreed one-off set up costs.</p>
<p>7.4</p>	<p>Which vaccine-related consumables will be provided to pharmacy contractors free-of-charge?</p>	<p>Linked consumables for the vaccine will be supplied with the vaccine, including:</p> <ul style="list-style-type: none"> • Diluents for the vaccine, if required • Dilution syringes/needles (as required for the vaccine(s)) • Combined needle and syringes for administration of the vaccine(s)) <p>PPE will be supplied as part of the consumables drop to each site ahead of vaccine deliveries and contractors do not need to source this via the DHSC portal which should be used by them for their COVID-19 related PPE supply to deliver their usual pharmaceutical services</p>

7.5	How will pharmacy contractors be paid for administering vaccinations?	<p>Payment is usually on the second dose, subject to some exceptional circumstances where pharmacy contractors can claim payment for a single dose which will be specified within the LES agreement.</p> <p>Activity information will be generated from the vaccination event data pharmacies will record on the Pinnacle and Sonar PoC system. Claims should be made each month through the Manage Your Service (MYS) system. Payments will be made by the NHS Business Services Authority.</p>
7.6	Is there separate funding for time to use PPE?	This is incorporated in to the IoS fee
7.7	Is there any additional funding for unsocial hours working?	This is incorporated in to the IoS fee
7.8	Is there any additional funding for overtime?	This is incorporated in to the IoS fee
8	Reporting and information sharing	
8.1	What specific information do we need pharmacy contractors to record about administration of the vaccines?	<p>To be confirmed but likely to include:</p> <ul style="list-style-type: none"> • First or second vaccination • Vaccine type • Manufacturers' expiry date • Batch number • Use by date (after defrosting, if applicable) • Name of person drawing up • Name of person administering • Date and time of administration • Site of administration (eg. left or right deltoid) • Any adverse events

8.2	What reporting will contractors need to undertake?	We will confirm reporting arrangements soon. Contractors should plan that reporting will include daily and <i>ad hoc</i> requests, including contributing to regional / STP readiness reports; monitoring, reporting and responding to early warning triggers and mitigations; and incident reporting.
8.3	How will pharmacy contractors be informed if their patient has been vaccinated by another provider?	We will confirm this soon, but we expect that the electronic pharmacy record will update the National Immunisation Management System (NIMs), which will update the GP record in near real-time when a patient is vaccinated. Further details will be shared in due course.
9	Further information	
9.1	How will pharmacy contractors be informed of vaccine programme developments ie when further information is available such as publication of clinical guidance documents and eligible cohorts coming on stream?	<p>Pharmacy contractors delivering the LES must sign up to receive the NHS England and NHS Improvement Primary Care Bulletin if they have not already done so, so key information in relation to the delivery of this service can be communicated in a timely manner. Pharmacies can sign up to the Bulletin at: https://www.england.nhs.uk/email-bulletins/primary-care-bulletin/</p> <p>Space has been set up for the COVID-19 Vaccination Programme on the FutureNHS workspace (registration required).</p> <p>We will also use other routes such as Ministerial announcements and communications from our national and regional teams or via LPCs or PSNC to keep contractors informed.</p>