

**Letter on urgent preparing for general practice to contribute to a potential covid-19 vaccination programme**

**ANNEX A: Indicative Enhanced Service Specification: COVID-19 Vaccination Programme 2020/21**

**Reference Guide**

9 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.

The BMA General Practitioners Committee in England has now agreed with NHS England and NHS Improvement the general practice COVID-19 vaccination service which will be commissioned in line with agreed national terms and conditions as an enhanced service (ES).

An indicative ES service specification will be published shortly. This table indicates the likely content of the indicative ES specification to support practices to start planning. It should be read in conjunction with guidance on the **General Practice Site Designation Process: Covid-19 vaccination programme 2020/21**.

Where **PCN grouping** is mentioned in this document we are referring to practices that collaborate to deliver the services under the ES, which may include established primary care networks (PCNs), and additional neighbouring practices and/or other groups of practices working together.

	FAQs	Planning assumptions
<b>1</b>	<b>Eligible cohorts</b>	
1.1	<p><b>Which cohorts are included in the general practice specification?</b></p>	<p>Aspects of a potential COVID-19 vaccination programme will be finalised when final trial results and licensing has occurred. The JCVI will then finalise cohort prioritisation, and which vaccines are most suitable for different cohorts. The JCVI has already set out draft prioritisation and the order in which eligible adult cohorts should be vaccinated.</p> <p>General practice will have a particularly important role to play in contributing to administering vaccinations to ‘at risk’ patients, care home residents and staff, those aged 50 and older as well as general practice and other primary care staff and care home staff workers. Practices will need to align vaccination delivery with the national timetable for the call/recall of eligible cohorts.</p> <p>Once patients are notified by the national call/recall service they are eligible for a vaccination, they would have the choice to book an appointment at a general practice-led vaccination centre or, use the National Booking Service to be vaccinated by another provider. PCNs will have the option of joining national direct booking arrangements if they wish and commit to meeting the additional requirements involved.</p> <p>Similar to the arrangements in place under the PCN DES, practice staff will be able to vaccinate patients who are registered with another practice within the PCN grouping, subject to the appropriate formal agreements being in place, eg the Collaboration Agreement/Staff sharing agreement. NHS England and NHS Improvement will provide a template COVID-19 Enhanced Service Vaccination Collaboration Agreement for PCN groupings to use.</p>

<p><b>1.2</b></p>	<p><b>Will eligible patients be able to choose where they are vaccinated?</b></p>	<p>Subject to available supply and availability of appointments, the majority of patients will be able to choose where they are vaccinated. We expect many patients will want to be vaccinated in general practice due to existing, trusted relationships.</p> <p>If multiple doses of the same COVID-19 vaccination are required, these must be administered by the same provider / designated site (unless there are exceptional circumstances which will be listed in the service specification).</p>
<p><b>1.3</b></p>	<p><b>What are the eligibility criteria for high and moderate risk patients?</b></p>	<p>The eligibility criteria will be confirmed by JCVI in due course.</p>
<p><b>1.4</b></p>	<p><b>Will practices be able to vaccinate their own practice staff even?</b></p>	<p>Once eligible for a COVID-19 vaccination, practice staff will be eligible for vaccination under the Enhanced Service and able to choose to be vaccinated at the designated site of their PCN grouping or by another provider – regardless of whether they are registered as a patient at a practice within the PCN grouping or not.</p> <p>The Clinical Negligence Scheme for General Practice (CNSGP) provides clinical negligence indemnity cover for all staff engaged by a GP practice. It covers NHS activities delivered under a Primary Medical Care contract, an NHS standard Contract with Schedule 2L or for other NHS services provided by the practice which are ‘Ancillary Health Services’ such as an Enhanced Service. Cover under CNSGP is not restricted to a GP’s registered patients so would apply to the provision of an Enhanced Service (ES) by a GP Practice to a person such as practice staff who are not on the registered list of that practice.</p> <p>The ES service specification will require practices to have a collaboration agreement in place that ensures CNSGP applies. NHS England will provide a template collaboration agreement</p>

		for practices to use that will cover the indemnity implications of practices vaccinating each other's patients, their own practice staff and non-registered patients.
<b>1.5</b>	<b>Who will provide services for health inclusion groups, eg homeless people?</b>	We expect that commissioners will commission local services for health inclusion groups, eg homeless people, but general practice may have a role to play in some local areas.
<b>1.6</b>	<b>Will general practice be required to vaccinate housebound patients as part of home visits?</b>	<p>Yes, as per the flu specification, the COVID-19 ES specification will state: "Where the patient or parent/guardian where appropriate, has indicated they wish to receive the vaccination but is physically unable to attend the designated site (for example is housebound), the practice must make all reasonable effort to ensure the patient is vaccinated." Commissioners should support practices to work with community partners and other local providers as appropriate to identify pragmatic local solutions to vaccinating these 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 and their community partners, making every contact count, eg in relation to housebound patients.</p>
<b>2</b>	<b>Collaboration requirements</b>	
<b>2.1</b>	<b>Can all practices sign up to deliver the enhanced service?</b>	All practices will have the opportunity to sign up to participate in the enhanced service but in doing so, they are agreeing to deliver the requirements of the enhanced service. A key requirement is that the practice has access to a local vaccination site that meets the core requirements for COVID-19 vaccination, which will be confirmed via a site designation

		<p>process. Practices will need to collaborate in their ‘PCN grouping’ and nominate a single site in the local area to be designated to deliver COVID-19 vaccinations.</p> <p>On publication of the final service specification, commissioners will invite practices with access to a designated site to sign up to deliver the COVID-19 Vaccination Programme Enhanced Service.</p> <p>Practices will need to put in place a COVID-19 Enhanced Service Vaccination Collaboration Agreement which sets out how they will work together to deliver COVID-19 vaccinations at scale to the eligible cohorts. We will publish a template COVID-19 ES Vaccination Collaboration Agreement, which the PCN grouping may wish to use and adapt. We will engage the GPC in the development of the national template.</p>
<p><b>2.2</b></p>	<p><b>What will the Covid-19 Enhanced Service Vaccination Collaboration Agreement need to cover?</b></p>	<p>All practices must have in place a COVID-19 ES Vaccination Collaboration Agreement signed by all collaborating practices in its PCN grouping that as a minimum contains provisions in relation to the following:</p> <ul style="list-style-type: none"> <li>• appropriate arrangements for patient record sharing in line with data protection legislation</li> <li>• appropriate arrangements for reporting of activity data, vaccine stock, available capacity and submission of required data to commissioners as well as communicating with patients, including but not limited to call/re-call</li> <li>• arrangements for the sharing and deployment of staff in relation to the efficient delivery of the services pursuant to this ES</li> </ul>

		<ul style="list-style-type: none"> <li>• financial arrangements between the collaborating practices and if relevant, financial arrangements relating to other healthcare providers (such as community pharmacies) outside its PCN grouping involved in local delivery of the ES</li> <li>• arrangements in relation to use of the Designated Site and any other relevant premises (as required)</li> <li>• sub-contracting arrangements (as required)</li> <li>• the arrangements for practices vaccinating patients registered with another practice in their PCN grouping, their own practice staff and unregistered patients, which ensures CNSGP cover applies.</li> </ul> <p>We will publish a template COVID-19 ES Vaccination Collaboration Agreement, which the PCN grouping may wish to use and adapt. We will engage the GPC in the development of the template.</p>
<b>3</b>	<b>Designation process and timescales</b>	
<b>3.1</b>	<b>What is the designation process and criteria?</b>	Please refer to guidance document entitled: <b>General Practice Site Designation Process: COVID-19 vaccination programme 2020/21.</b>

4	<b>Call and Recall / Appointment booking / Comms</b>	
4.1	<b>Will there be a national call-recall system?</b>	Yes. All 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.
4.2	<b>What is the ask of general practice in supporting national call/re-call?</b>	<p>In addition to the national call/re-call service, PCN groupings will be asked to write out/text and as appropriate call their patients using standard text determined nationally. Practices will not be contractually obliged to offer call and recall for cohorts that they are unable to reliably identify from their records, eg, health and social care workers. However, where eligible patients in these cohorts are identifiable, practices are strongly encouraged to contact patients and invite them for vaccination at the point they become eligible.</p> <p>Practices will have the option of joining national direct booking arrangements if they wish and commit to meeting the additional requirements involved.</p>
4.3	<b>Will practices need to share their patient lists with the national call and re-call system?</b>	No, there will be a national extraction.
4.4	<b>What are the expectations of practices if patients don't respond to their invitation?</b>	Practices may be asked by the national programme or regional team to contact targeted groups again if uptake is low. Practices will need to ensure they use all vaccinations that have been made available to them. They will need to proactively reach out to eligible patients

		<p>if in exceptional circumstances they do not think they will not be able to use their supply of vaccinations in sufficient time.</p>
<b>4.5</b>	<b>How would vaccines be ordered by practices/PCNs?</b>	<p>There will be a strict system for ordering based on national allocations. The national programme will share guidance on this soon.</p> <p>The national programme will seek to ensure that the principal of equivalence applies, and that general practice will be given fair access to available vaccine supply, rather than this being determined by another provider.</p>
<b>4.6</b>	<b>How will patients book appointments?</b>	<p>Practices should advise patients how to book an appointment in their call/recall communications.</p> <p>If PCN groupings do not opt into the National Booking System, they will be responsible for managing their own appointment booking systems and scheduling clinics in accordance with vaccination supply. If PCN groupings opt into the National Booking System, they will need to comply with the additional requirements involved.</p> <p>Currently there is no way of informing practices automatically when a patient books a vaccination with another provider via the National Booking System, but we are looking into this further.</p>
<b>4.7</b>	<b>What advice and support will be made available to patients pre and post vaccinations?</b>	<p>This will be confirmed in due course, but PHE is expected to produce pre and post vaccination materials that practices will be able to use.</p>



5	<b>Preparation and administration of the vaccinations</b>	
5.1	<b>From which date will practices be expected to deliver vaccinations to eligible cohorts?</b>	<p>Even though we do not yet know when the first vaccination will become available, it is critical that general practice is ready to administer vaccinations from as early as December.</p> <p>When vaccines come on stream, practices will need to align vaccination delivery with 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.</p>
5.2	<b>How can vaccinations be given to a patient who lacks capacity to give or withhold consent themselves?</b>	<p>There will be a national consent form available as part of the PHE documentation. The consent process for a patient who lacks capacity to give or withhold consent themselves needs to be undertaken prior to the day of vaccination – therefore the process needs to begin early.</p>
5.3	<b>What preparation of the vaccine is required?</b>	<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>Practices should plan on the assumption that vaccines will come in multi-dose vials, will need drawing up and may require dilution. Practices should also assume that there may be additional requirements, such as limits on time at ambient temperature and limits on time at 2-8 degrees Celsius before use.</p>
5.4	<b>What clinical guidance will be made available?</b>	<p>Training materials will be made available from PHE/HEE. Standard Operating Procedures will be published, along with clinical guidance.</p>

<b>5.5</b>	<b>Will there be a national PGD?</b>	Yes, there will be a national PGD and a protocol for using an expanded vaccinator workforce.
<b>5.6</b>	<b>What PPE do staff need to wear?</b>	The requirement is to follow the national guidance on IPC for vaccinations in a mass vaccination site and when attending a patient in their home or care home.
<b>5.7</b>	<b>What observation period is required post vaccination? And who will observe the patients?</b>	JCVI will confirm this in due course, but practices should plan on the assumption that an observation period is required post vaccination, in a socially distanced space.
<b>5.8</b>	<b>How many doses of the vaccines will be required?</b>	JCVI will confirm this in due course but practices should plan on the assumption two doses of the <u>same</u> vaccination will be required. JCVI will also confirm the relevant maximum and minimum timescales for administration of each vaccine, where multiple doses are required.
<b>5.9</b>	<b>How soon can a COVID-19 vaccination be administered after a flu vaccination?</b>	This will be confirmed in due course, but practices should plan on the assumption there needs to be at least 7 days between the flu vaccination and COVID-19 vaccinations.
<b>6</b>	<b>Workforce</b>	
<b>6.1</b>	<b>Who can administer the jab?</b>	The Statutory Instrument <sup>1</sup> allows the vaccine to be administered according to a two-step national protocol using registered healthcare professionals to carry out the clinical assessment, consent and preparation and a suitably trained non registered member of staff will be able to administer the vaccine itself under clinical supervision by a registered

<sup>1</sup> Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 [https://www.legislation.gov.uk/uksi/2020/1125/pdfs/uksi\\_20201125\\_en.pdf](https://www.legislation.gov.uk/uksi/2020/1125/pdfs/uksi_20201125_en.pdf)

		healthcare professional. The Statutory Instrument does not specify who these non-registered vaccinators might be. This will be covered in the protocol which will be published soon.
<b>6.2</b>	<b>What are the training requirements for staff administering COVID-19 vaccines?</b>	<p>All staff involved in administration of COVID-19 vaccines will need to complete the relevant training provided by PHE/HEE. Practices will be expected to oversee and keep a record to confirm that all staff have undertaken the training prior to participating in vaccinations. Otherwise the training requirements are expected to mirror those in the flu specification.</p> <p>There will be a COVID-19 vaccination programme overview pack for all staff that can be used for onboarding.</p>
<b>6.3</b>	<b>How would practices access COVID-19 vaccination training? How long will the training take?</b>	National e-learning will be available on e-learning for healthcare – it is likely that most practice staff will only be required to undertake COVID-19 vaccine specific chapter(s) of the online training package. We anticipate a chapter could take up to a maximum of 1.5 hours but further details will be shared soon. If and when any additional vaccines become available, a new chapter will be added to the e-learning materials for each new vaccine.
<b>6.4</b>	<b>What additional workforce will be made available for practices to draw down on?</b>	Practices will need to provide the majority of the required staff from their own workforce, though additional workforce, including volunteers may be available through agreed national frameworks or through any existing local channels (that practices may have access to during flu season). If practices want to use the Bring Back Staff Scheme (BBS) and GP returners, they should liaise with regional BBS leads to identify CVs and availability. Our current understanding is that practices would be required to employ or engage any of these staff directly and pay Agenda for Change Terms and Conditions.

		<p>More detail will be shared on how practices can access support from volunteers and additional workforce.</p> <p>A template honorary contract and template workforce sharing agreement will be developed and the BMA will be engaged in the development of these.</p> <p>Our shared ambition is for general practice to remain fully open and accessible to all patients. Separately NHS England and NHS Improvement has announced additional non-recurrent funding of £150 million to expand general practice capacity between now and March 2021. We also recognise that the additional workload of a COVID-19 vaccination programme may require practices to prioritise clinical workload. Further reassurance on income is provided by the existing funding guarantee for the QOF in 2020/21.</p> <p>As part of local clinical prioritisation, we would urge local providers and CCGs to repurpose extended hours capacity to provide full support for potential COVID-19 vaccination activity. We also expect CCGs to take sensible decisions around the re-purposing of funded capacity delivering locally enhanced services which could also be paused.</p>
<p><b>6.5</b></p>	<p><b>Will stewards be available to support designated vaccination sites?</b></p>	<p>This will be down to the features of the individual site, local preference and requirements. Practices should use local relationships and resources where possible, though drawdown on national frameworks can be discussed with the regional workforce lead provider.</p> <p>PCN groupings will need to assess the need for security at their designated site and respond appropriately.</p>

7	Funding	
7.1	<p><b>What is the Item of Service (IoS) fee?</b></p>	<p>The national programme will seek to ensure that the principal of equivalence applies between general practice and other providers, eg on funding, and that general practice will be given fair access to available vaccine supply rather than this being determined by another provider.</p> <p>We have agreed with the BMA GPC that the Item of Service fee will be £12.58 per vaccination, which is 25% more than the current fee for service for an influenza vaccination, at £10.06. This additional 25% payment 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> <p>There will be no other national funding available, although local commissioners may be able to help with one-off costs. In particular, CCGs have provided additional support to general practice to support the flu programme (eg additional venue hire) and we expect to be able to make some limited funding available to extend these arrangements for a potential COVID vaccine programme.</p>
7.2	<p><b>What if practices are unable to administer a completing dose of the vaccine, would they be</b></p>	<p>An exceptions process will be in place for those patients for whom the completing dose is inappropriate, in which case a payment for a single dose will be made (£12.58). The specification will confirm the exception criteria, but this is likely to include:</p> <p style="padding-left: 40px;">(a) unsuitability for the patient:</p>

	<p><b>paid for the dose they had administered?</b></p>	<ul style="list-style-type: none"> <li>(i) because of medicine intolerance or allergy discovered during administration of the first dose</li> <li>(ii) if the patient has commenced end of life care before a second dose of the vaccine could be provided</li> <li>(iii) if the patient has died before a second dose could be provided.</li> </ul> <ul style="list-style-type: none"> <li>(b) patient choice, the patient has chosen not to receive the second dose of the vaccine following a shared decision making conversation</li> <li>(c) no response, the patient did not respond to offers of receiving a second dose of the vaccine</li> <li>(d) if the patient has moved out of the area covered by the PCN Grouping; or</li> <li>(e) if the patient has moved in to the area covered by the PCN Grouping after receiving the first dose of the vaccine from another provider.</li> </ul> <p>Practices must record the relevant qualifying criteria in accordance with the reporting requirements which will be published.</p>
<p><b>7.3</b></p>	<p><b>Will there be any additional sources of funding available in addition to the IoS fee?</b></p>	<p>There will be no other national funding available, although local commissioners may be able to help with one-off costs. In particular, CCGs have provided additional support to general practice to support the flu programme (eg additional venue hire) and we expect to be able to make some limited funding available to extend these arrangements for a potential COVID-</p>

		19 vaccine programme. Also, if a PCN grouping needs extra fridge space beyond what they have for flu, programme funding will be available.
7.4	<b>Which vaccine-related consumables will be provided to practices free-of-charge?</b>	<p>Linked consumables for the vaccine will be supplied with the vaccine, including:</p> <ul style="list-style-type: none"> <li>• diluents for the vaccine, if required</li> <li>• dilution syringes/needles (as required for the vaccine(s))</li> <li>• combined needle and syringes for administration of the vaccine(s))</li> </ul> <p>In addition, PPE will be available through the portal.</p>
7.5	<b>How will practices be paid for administering vaccinations?</b>	We will share further details on how payments will be made in due course.
<b>8</b>	<b>Reporting and information sharing</b>	
8.1	<b>What specific information will need practices to record about the administration of vaccinations?</b>	<p>To be confirmed but likely to include:</p> <ul style="list-style-type: none"> <li>• vaccine type</li> <li>• batch number</li> <li>• dose</li> <li>• name of person drawing up</li> </ul>

		<ul style="list-style-type: none"> <li>• name of person administering (if different)</li> <li>• date and time of administration</li> <li>• site of administration (ie left or right deltoid)</li> <li>• any adverse events</li> </ul>
<b>8.2</b>	<b>What reporting will practices need to undertake?</b>	We will confirm reporting arrangements soon.
<b>8.3</b>	<b>How will practices be informed if their patient has been vaccinated by another provider?</b>	We will confirm this soon, but we expect NIMs will update the GP record in near real-time when a patient is vaccinated.
<b>9</b>	<b>Further information</b>	
<b>9.1</b>	<b>How will practices be informed of vaccine programme developments i.e. when further information is available such as publication of clinical guidance documents and eligible cohorts coming on stream?</b>	<p>Practices delivering the ES will also be required via the service specification (if they have not already done so) to sign up to receive the NHS England and NHS Improvement Primary Care Bulletin so key information in relation to the delivery of this service can be communicated in a timely manner. Practices can sign up to the Bulletin at: <a href="https://www.england.nhs.uk/email-bulletins/primary-care-bulletin/">https://www.england.nhs.uk/email-bulletins/primary-care-bulletin/</a>.</p> <p>We will also use other routes such as Ministerial announcements and communications via commissioners and professional bodies to keep practices informed.</p>