

**Urgent preparing for general
practice to contribute to a
potential COVID-19
vaccination programme:
Annex B: General practice
site designation process**

COVID-19 vaccination programme 2020/21

9 November 2020

General Practice Site Designation Process

COVID-19 vaccination programme

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Equalities and health inequalities statement

"Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it;
- given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way where this might reduce health inequalities."

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If you have any queries about the designation process, please send these to england.cov-primary-care@nhs.net

1 Introduction

- 1.1 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. General practice will have an important role in a potential COVID-19 vaccination programme, alongside other providers. The BMA General Practitioners Committee in England has now agreed with NHS England the general practice COVID-19 vaccination service which will be commissioned in line with agreed national terms and conditions as an enhanced service (ES).
- 1.2 An indicative service specification will be published shortly and a final specification will be issued as soon as final details are clear
- 1.3 A key requirement of practices wishing to deliver COVID-19 vaccination under the Enhanced Service is that the practice has access to a local vaccination site that meets the core requirements for COVID-19 vaccination. Due to the specific supply, storage, preparation and administration characteristics of the vaccines as well as ongoing social distancing rules, it is essential that all sites delivering COVID-19 vaccination meet these core requirements.
- 1.4 A designation process has been established to provide assurance to the commissioner that all general practice-led sites administering COVID-19 vaccination under the ES meet the required site designation criteria.
- 1.5 This document sets out the designation process and is aimed at:
 - **Practices** working within their established PCNs or an established PCN collaborating with a non PCN member practice or another PCN for the purposes of delivering the COVID-19 Vaccination Enhanced Service 2020/21 and who within their 'PCN grouping' have nominated a site to be designated for delivering COVID-19 vaccinations under the ES.
 - **CCG teams** who will undertake on NHS England's behalf and in collaboration with PCN groupings an assessment of the nominated sites as part of the designation process and make a recommendation to the relevant NHS England and NHS Improvement regional team as to whether a site should be approved as meeting the designation criteria. In addition to supporting the assessment as to whether an individual site meets the designation criteria, CCGs will prioritise the list of sites in its geographical area it is recommending to NHS England for designation, considering

whether the recommended sites provide equitable access for its local population.

- **NHS England and NHS Improvement regional teams** (as NHS England is the commissioner of the Enhanced Service) who will review the recommendations of CCGs and take a decision as to whether a nominated site should be approved. In taking its decision, NHS England will consider whether the total number and geographical distribution of sites recommended by CCGs supports fair and equitable access for patients and can be supported by local COVID-19 vaccination supply chains. Where the number of recommended sites exceeds the number that can be accommodated, NHS England will prioritise the list of sites accordingly.

1.6 Due to the likelihood of complex logistics in this new supply chain, where a practice agrees to participate in this enhanced service, it will need to work collaboratively with other practices to deliver vaccinations in PCN groupings, and we anticipate at least one site being designated initially per PCN grouping. Those sites will need to collaborate with other community vaccination providers, as part of a coordinated local approach.

1.7 Practices are expected to collaborate within their PCN grouping, to nominate a single premises to be designated as the nominated vaccination site for those practices. However, the exact configuration needs to reflect the variable size of the population to be covered by the PCN grouping so in exceptional circumstances more than one site may be nominated subject to commissioner approval and vaccination supply eg, if the population size of the PCN grouping exceeds 100,000. A separate form should be completed for any additional sites and PCN groupings recommending more than one site should indicate an order of preference to the CCG. We expect around 1,000-1,500 general practice sites to be designated initially and if the total number of sites recommended for approval exceeds the number that can be accommodated by the local supply chain, the sites will need to be prioritised.

1.8 It is likely that later in the vaccination process, additional sites will be designated. These sites would also need to go through the designation process outlined in this document.

1.9 If PCN groupings are not able to identify an appropriate vaccination site to nominate or if their nominated site does not meet the criteria for designation, they will be expected to collaborate with their neighbouring PCN groupings to identify a site.

- 1.10 Once designated, all sites will be required to continue to meet the designation criteria for so long as required in the ES Service Specification. The commissioner should be informed immediately if for any reason, a designated site ceases to meet the criteria.
- 1.11 Upon 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.
- 1.12 Decisions on the supply of vaccine to designated sites will be taken by the national COVID-19 Vaccination Programme, to maximise access to priority groups set by government on the basis of the Joint Committee on Vaccination and Immunisation's (JCVI) advice. Designation of a site does not guarantee any specific vaccine delivery schedule.

2 Timescales

2.1 The designation process for the initial nominated sites will be undertaken according to the following timescales:

Date	
Monday 9 November	Designation process and criteria published
Wednesday 11 November	Briefing session for NHS England and NHS Improvement Regional Teams and CCGs on Designation Process
Tuesday 17 November	Deadline for PCN groupings to advise CCGs of nominated site for designation. <i>(Note that where PCN groupings submit nominations earlier the designation process can commence. PCN groupings are strongly advised to discuss their likely nominations with the CCG in advance of submitting the form).</i>
Thursday 19 November	Deadline for CCGs to have completed designation assessment process for nominated sites and submit recommendations to NHS England regional teams.
Friday 20 November	NHS England regional/national consideration of CCG recommendations and decision on which sites will be designated.
Monday 23 November	NHS England decision communicated to PCN groupings.
Late November	Final service specification published

3 Designation process

- 3.1 PCN groupings should read this document carefully before completing Section 1 of the General Practice Site Designation Process Form (Annex B). This section requires the details of the site being nominated for designation and the names and contact details of all of the practices/PCNs collaborating within the PCN grouping who have agreed that the nominated site will be used to administer COVID-19 vaccinations to their patient population. The form also requires a PCN grouping contact with whom the CCG can liaise throughout the designation process.
- 3.2 It is expected that PCN groupings will where possible, use existing premises within their collaborating practices' control. However, if this is not possible it will be expected to nominate alternative premises or work with a neighbouring PCN grouping to access a conveniently located site.
- 3.3 PCN groupings are asked to also provide (to help with local planning) an indicative number of vaccinations they believe the site will be able to deliver each week (sites will not be held to this number), recognising that the minimum number required is 975 vaccinations per week.
- 3.4 The completed form should be submitted to the relevant CCG lead no later than 4pm on **Tuesday 17 November**. Note that where PCN groupings submit nominations earlier, the designation process can commence. PCN groupings are strongly advised to discuss their likely nominations with the CCG in advance of formally submitting their site nomination.
- 3.5 Where the PCN grouping believes there are exceptional circumstances which mean it wishes to nominate two sites eg, because the PCN grouping's population is over 100,000, it should submit a separate form for the additional site but indicate to the CCG its order of preference.
- 3.6 In collaboration with the PCN grouping's nominated contact (who will involve other representatives from the relevant practices as appropriate), a CCG representative will then undertake a process to assess the extent to which the nominated site meets each of the specified criteria set out in Section 2 of the Form. This may be done remotely by a CCG representative familiar with the nominated site. CCGs are strongly encouraged where possible to engage the PPI lay member of the CCG in the process to reflect patient involvement duties. When considering criteria relating to accessibility and equality of access, the CCG should take account of the needs of the local population including specific

health inclusion groups. The CCG representative will record on the form their view as to whether each of the specified criteria has been met.

3.7 Nominated sites that do not meet all of the designation criteria cannot be recommended for designation. PCN groupings should note that even if a site is assessed by a CCG 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 need to be considered.

3.8 Once all site assessments are complete, the CCG should consider the total number of sites in its geographical area that have been assessed as meeting the designation criteria, and consider which sites it wishes to put forward to the regional team factoring in:

- equity of patient access
- achieving good geographical coverage
- where PCN groupings have nominated more than one site, whether there is a clear rationale for this eg, population is over 100,000. If not, only one site should be recommended for approval, ensuring that a consistent approach has been taken where the CCG is recommending that more than one site should be designated for PCN groupings.

3.9 The CCG representative should complete section 3 of the form for the sites they are recommending for approval. This includes a requirement for the CCG to indicate the priority for approval it has attached to the site eg, site is priority 21 out of a total of 30 sites recommended by CCG for approval. This information will be used to prioritise sites for approval where the number of sites recommended by CCGs exceeds the numbers that can be accommodated within the supply chain in that Region. The form will be sent to the relevant NHS England Regional Team no later than 4pm on **Thursday 19 November**.

3.10 On **Friday 20 November**, NHS England Regional Teams will present the outcome of the assessments and list of sites recommended for designation to each other and relevant members of the NHS England national primary care and COVID-19 vaccination teams to ensure that a fair and consistent approach has been taken in all areas (including patient access, geographical distribution,

multiple PCN grouping sites and supply chain). The final decision on which sites have been designated will be communicated in writing by NHS England regional teams to CCGs and PCN groupings on **Monday 23 November**.

- 3.11 In discussion with the CCG, initial nominated sites must have completed the designation process prior to the 1 December 2020 (or prior to vaccine delivery for subsequent sites).
- 3.12 As vaccine supply generally increases over time, we anticipate expanding the number of sites and PCN groupings may subsequently be invited by the commissioner to nominate additional premises. These sites would also need to go through the designation process outlined in this document. PCN groupings – with agreement from the local CCG – may wish to indicate the location of these additional sites now so that once the designation process for the initial nominated sites is complete, additional sites can be assessed and brought on stream rapidly (where they have been judged to meet the designation criteria and the supply chain allow). A separate form should be completed for any additional sites that the PCN grouping wishes to nominate and it should be clearly marked on the form that it relates to a **FUTURE SITE NOMINATION**.

Annex A

Designation Criteria

#	Criteria	Requirements
1	Storage	<p>1.1 Fridge space to store (2-8c) or confirmed plans to have fridge capacity in place no later than 1 December and capacity to administer minimum of 975 doses per week (or greater in accordance with minimum ordering requirements for specific vaccines and ensuring all doses are administered within appropriate shelf life)</p> <p>1.2 PPE and other consumables (including linked consumables specifically diluent needle and syringe and combined needle and syringe)</p>
2	Planning and co-ordination	<p>2.1 Ability to coordinate clinical capacity in line with cohort prioritisation and national/practice call/recall schedules and in alignment with national communications guidance, whilst maintaining appropriate levels of wider general practice capacity.</p> <p>2.2 Ability to deliver vaccinations 7 days a week from 8am to 8pm, including potentially on bank holidays if required.</p> <p>2.3 Capacity and capability to coordinate with the regional/STP operations centre to plan clinics according to expected vaccine supply, coordinate required trained staff, order required vaccine and consumables supply within required timeframes, receive and safely and securely store supply, amend clinic schedule if there is a disruption to supply and liaise with practices to undertake timely communication of any changes to patients.</p> <p>2.4 Ability to coordinate clinics around the different types of vaccine to ensure patients receive the full course of the appropriate vaccine.</p>

		2.5 Ability to accommodate new vaccine types as they become available.
		2.6 Ability to work with community partners and local CCGs on local delivery plan to ensure best use of local resources and clinic schedules that offer patients flexibility and choice.
3	Site Safety	3.1 Ability to ensure smooth entry and exit from the building complying with social distancing and current COVID-19 guidance, with appropriate security arrangements, providing stewards if needed and ensuring there are adequate parking arrangements. The impact on the local community should also be considered.
		3.2 Ability to comply with required assurance process if using a non practice premises to deliver vaccination clinics.
4	Wastage	4.1 Ability to plan and deliver clinics with minimum wastage and certainly never more than 5%.
		4.2 Appropriate disposal of all clinical waste.
5	Space	5.1 Physical layout that will support administration of the minimum weekly volume, complying with social distancing and with space for post-vaccination observation.
6	Workforce	6.1 Liaise with the local lead workforce provider regarding any additional workforce requirements that can be accessed through the national frameworks.
		6.2 If non-registered staff are to be used to administer vaccines they must be working under clinical supervision and the national protocol (to be published).
		6.3 Ensure clear plan in place to provide adequate staff for clinics.

7	Patient Experience	7.1 Ability to provide appropriate information, advice and decision support to patients coming for vaccination, including relevant pre/post vaccination materials, recognising these needs will be greater than with other routine vaccinations. Provide information online.
		7.2 Ability to support patients with additional needs, including access, language or communication.
		7.3 Complete equality impact assessments for clinic plans as appropriate where the nominated site is not an existing practice site.
8	Vaccine storage and handling	8.1 Ability to fully comply with all storage and handling requirements, including maximum allowable time at 2-8c before administration and time between dilution and administration.
9	Preparation	9.1 Appropriate space and trained workforce to prepare the vaccine which will include dilution where required, using standard aseptic technique, and drawing up of multi-dose vials in all cases.
10	Administration	10.1 Ability to administer vaccines safely in accordance with IPC guidance in all settings
11	Aftercare	11.1 Ability to provide post-vaccination observation of 15 minutes, compliant with social distancing and with access to necessary equipment and trained staff to provide immediate response to an adverse event
12	Data collection	12.1 Sites will be required to comply with point of care data collection requirements. (Specific arrangements to be confirmed in the service specification). Each site will need to ensure there is appropriate access to the relevant system to record the vaccination event the same working day as the vaccine administration occurs and that all staff are trained and have the relevant access to support timely data collection.
13	Reporting	13.1 Contributing to regional/STP readiness assessments; monitoring, reporting and responding to the early warning triggers and mitigation; reporting incidents; responding to daily and hoc requests for intelligence and information.