### Covid-19

## Guidance for practices



Date: 04.12.2020 Please be aware that this is a rapidly evolving situation.

#### NHS Enhanced Service Specification – Covid Vaccination Programme 2020/21 – practice guidance

On the evening of 1 December 2020 NHS England published two documents: the <u>Enhanced Service (ES) Specification</u> for practices who wish to participate in the national Covid-19 Vaccination Programme (CVP) and an accompanying explanatory letter entitled "<u>Covid-19 Vaccination programme 2020/21 – next steps</u>". These two documents are available alongside <u>other NHS England guidance here</u>.

Below is our analysis of the ES specification, with reference to specific paragraphs within it and the accompanying NHS England letter, along with our commentary on what they practically mean for practices and PCN groupings. The key requirements of the specification and relevant timelines are highlighted, potential risks for practices/PCNs are identified and where there is lack of clarity or further information is awaited, this is stated as well. Please consider the information in this guidance and in the two attached NHSE documents carefully before you decide whether to sign up to the ES.

### The deadline for signing up to the ES is 23:59 on Monday 7 December 2020 and practices who wish to opt in must notify their CCG by email. Participation in this ES is optional for practices.

Please note that even though delivery of this ES is expected to be through practice collaboration at PCN level, the decision to participate in this ES must be made at practice level, which means that each practice who wishes to sign up must do this directly with their CCG. It is not for PCNs to do this on behalf of their member practices.

Key contractual and service delivery requirements and relevant timescales are in the following table.

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Paragraph in the specification	What the specification says	What this means for practices and PCN groupings – LMC comments
Introduction		
1.1 (and footnote 1)	This ES is made under Section 7A of the NHS Act 2006. NHSE remains responsible for discharge of the Section 7A functions.	NHSE is not delegating this ES to CCGs. Therefore, the specification cannot be changed or varied locally by CCGs.
1.2	NHSE has agreed this ES with the GPC. NHSE will agree future amendments with the GPC, unless it is necessary to amend it in line with recommendations or decisions of the JCVI, MHRA, vaccine manufacturers, or Ministers, where NHS England will discuss the required changes with the GPC.	GPC consent is not required in the circumstances described, which means that NHSE can impose changes to the ES unilaterally in those cases.
1.4 and 1.5	This ES is offered to all GMS, PMS and APMS practices. It covers aspects of enhanced clinical care and as such, does not define or re-define essential or additional services under primary medical service contracts. That said, those practices who decide to sign up to it,	Like the PCN DES, the Covid Vaccination Programme (CVP) ES, will be varied into the GMS, PMS and APMS contracts of those practices who decide to sign up to it. This means that the ES will be deemed to be part of participating
	agree that the provisions of this ES will be incorporated as a variation into their primary medical services contract.	practices' core contracts.
1.6	Participating practices will have to collaborate with others to deliver this specification. "The GP practice, in collaboration with other GP practices in the PCN grouping, must have the ability to deliver this ES during the hours of 8am to 8pm, 7 days per week and including on bank holidays. The Commissioner (NHSE) will inform practices where this is required"	This has understandably caused significant anxiety for practices. The accompanying letter from NHSE states regarding the need to operate 8-8, 7 days per week, that "it will only be required where the supply of vaccine necessitates this to ensure all of the vaccine available is being used to vaccinate patients as quickly as possible".

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1.6 cont.		Even though NHSE does not expect teams to be available 8-8, 7 days a week when vaccine supplies and volumes do not necessitate this, the fact remains that Designated Sites must have the facility to be operational 8 – 8 7 days per week, including Bank Holidays, at the direction to NHS England, based on the need to efficiently deliver available vaccine supplies.
		The BMA has issued the following advice on this: "The ES requires the designated vaccination site to be able to deliver vaccines seven days a week, this includes Christmas. This is because of the characteristic of the vaccine – i.e. limited shelf life, space between doses etc – but will also depend on patient demand and vaccine supply.
		It may be that very few patients want to receive the vaccine on Christmas Day, making delivery then impractical, or that the vaccine supply for the week has been expended before Christmas Day. Should a service take place, extended access services could be used".
1.7	All groups of participating practices must sign a Collaborative Agreement, a template of which will be provided by NHSE; details on what this Agreement should cover are provided under our note on paragraph 6.4	NHSE have confirmed they will be providing a national Indicative Collaborative Agreement template. The date this will be published is not yet known. We are monitoring this closely and will be providing further advice and guidance when the template is released.

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Paragraph in the specification	What the specification says	What this means for practices and PCN groupings – LMC comments
1.8	"Where this ES sets out a requirement or obligation of a PCN Grouping, each GP practice of a Primary Care Network together with neighbouring GP practices as described above, is responsible for ensuring the requirement or obligation is carried out on behalf of that PCN Grouping".	This means that each practice who has signed up to this ES is jointly and severally liable with the other practices in its PCN grouping for the delivery of this ES.
Background and c	luration	
3.1	<i>"This ES begins on 8 December 2020 and shall continue until 31 August 2021"</i> unless it is terminated earlier. (The circumstances under which it may be terminated earlier are listed in para 3.2).	This ES is intended to run for nine months. This means that practices who sign up to it should expect to commit to delivering this ES for a number of months, which should be taken into account when planning service delivery locally.
3.5	"The GP practice, together with the other GP practices in the PCN grouping shall be considered joint and several owners of the vaccine. [] GP practices support in relation to stock forecasting, use and ordering is important to this ES".	This follows on from para 1.8, which stipulates that practices are jointly and severally liable in their PCN grouping for the delivery of this ES. Para 3.5 enhances that by placing responsibility on practices as "joint and several owners of the vaccine" to manage stock, use and ordering of the vaccines. We understand this includes any costs incurred or financial liabilities involved.
3.6	"This ES will be updated from time to time as the vaccination programme develops and is subject to Ministerial Decision".	Changes or updates to this ES may occur at short notice and will take effect immediately. Details of the programme and updates will be published on <u>this NHSE web page</u> .

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Process		
4.1	Practices have up to 23:59 on Monday 7 December 2020 to sign up to this ES.	Practices have asked us whether this deadline is likely to be extended. We understand this has been discussed between NHSE and the GPC, but up to the time of publication of this guidance we have not received any confirmation or indication that there will be an extension to this deadline.
4.2	Participating practices must have access to a designated site. However, if a patient's medical condition requires that they be vaccinated at another site (e.g. in their home), practices must administer the vaccine at another location. Practices must also make arrangements to vaccinate patients in care homes, in their care home of residence.	Practices should consider the practical, resource and time implications of the requirement to vaccinate patients in their own home or their care home. The accompanying NHSE letter states on page 1 that practices have asked whether it will be possible to deliver the vaccination programme out of practice locations. This is not possible at the moment due to logistical issues to do with the supply and distribution of the vaccine, however this is being kept under review.
4.3	"Payment under this ES is conditional on GP practices: 4.3.1 entering into this ES, <u>including any variations and</u> <u>updates;</u> 4.3.2 complying with the requirements of this ES; and 4.3.3 completing the course of vaccinations to Patients (unless exceptional circumstances apply as set out at paragraph 11.3)".	This paragraph indicates that if practices fail to meet the requirements of variations to this ES imposed unilaterally by NHSE, it is possible that they may not be paid for work already done. It is important that NHSE and the GPC provide urgent clarification on this and also formal assurance that practices will be paid for all work already done.

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Paragraph in	What the specification says	What this means for practices and PCN groupings – LMC comments
the specification		
Collaboration req	uirements – general	
5.1.1	Practices are required to collaborate with other practices within their PCN grouping <i>"and outside of its PCN grouping (where appropriate)"</i> to deliver this ES specification.	Practices should be mindful that they may be asked to support other practices outside of their PCN grouping, if necessary.
5.1.2	Practices must share information with other practices within (or outside of) their PCN grouping as appropriate, for the purposes of delivery of this ES.	
5.1.3	Practices must "have regard to all relevant guidance published by the Commissioner (NHSE) or referenced within this ES".	This guidance has not been published yet, therefore it is not yet known what more practices will be required to comply with outside of the requirements already set out in this specification.
5.1.4	Practices must "take reasonable steps to provide information (supplementary to national communications) to Patients about the services pursuant to this ES"	This means that it will be the responsibility of practices to provide their patients with <i>"supplementary"</i> , ie additional information to national communications.
5.1.5	The practice must also "ensure that it has in place suitable arrangements to enable the lawful sharing of data to support the delivery of the services, business administration and analysis activities".	Legally appropriate data sharing agreements will need to be in place and participating practices should be mindful that they have responsibility to comply with GDPR requirements.
Collaboration req	uirements – PCN groupings	
6.4	"All GP practices must have in place a COVID-19 ES Vaccination Collaboration Agreement signed by all collaborating GP practices in its PCN Grouping by no later than the day before the date of the first administration of the vaccinations that sets out the clinical delivery model (i.e. how clinics are delivered and responsibility is shared	The requirements of this Collaboration Agreement are extensive. Please see our note on the next paragraph below.

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6.4 cont.	<ul> <li>between the GP practices within the PCN Grouping) deployed by the PCN Grouping and as a minimum contains additional provisions" and appropriate arrangements for: <ul> <li>patient record sharing;</li> <li>activity data recording and vaccine stock, use and forecasting;</li> <li>communicating with Patients, including but not limited to call/re-call;</li> <li>sharing and deployment of staff as agreed by the PCN grouping;</li> <li>financial arrangements between collaborating practices within and outside the PCN grouping as appropriate;</li> <li>use of the Designated Site and other relevant premises as required;</li> <li>sub-contracting arrangements as required;</li> <li>lead contact email address for the PCN grouping.</li> </ul> </li> <li>appropriate indemnity arrangements. The specification confirms that services provided under this ES are covered under the CNSGP scheme.</li> </ul>	

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6.5	NHSE will publish a template COVID-19 ES Vaccination Collaboration Agreement <u>here</u> (currently a non-live URL), which the PCN Grouping may wish to use and adapt for the purpose of delivering this ES.	NHSE has not published a template for this Vaccination Collaboration Agreement yet, nor have they indicated the date when this will be made available. They have stated it will be an "Indicative" agreement template, so it is not clear how much detail will be provided in it. In any case, we will review and provide guidance on this template as
		soon as practically possible after it is published by NHSE.
6.6	PCN groupings will be expected to collaborate with national and regional STP operation centres in relation to vaccine forecasting and ordering arrangements. They will also be required to comply with any requirements set out in relevant Standard Operating Procedures (SOPs).	It is possible that PCN groupings may be required to provide SitReps (Situation Reports) to their STP/ICS and also work alongside local mass vaccination sites.
Site designation		
7.8	"GP practices are responsible for ensuring that the quality and connectivity of internet broadband at the Designated Site is sufficient to support access to the point of care system 7 days a week between the hours of 8am and 8pm".	Ensuring internet connectivity at the Designate Site is a significant responsibility which is being placed on practices.
7.9	"Where NHSE requires the GP practices to put into place any reasonable security requirements regarding the vaccine and the Designated Site, the GP practice shall make all reasonable efforts to ensure that these requirements are put into place as soon as possible".	Security at the Designated Site will be practices' responsibility as well. Practices should consider the practical and resource implications of this requirement.

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the specification		
Sub-contracting a	rrangements	
8.1 and 8.3	NHSE acknowledges that practices may have to sub- contract delivery of clinical services under this ES to other practices within (or outside) of their PCN grouping. Practices wishing to sub-contract should do so in line with the sub-contracting provisions in their GMS/PMS/APMS contracts.	As long as subcontracting is done in accordance with the provisions of practices' core primary medical services contracts, NHSE will not object to it.
Service delivery s	pecification	
9.1	Commencement of vaccine delivery will be no less than 10 days following notification from NHSE.	
9.2	"Patients eligible to receive the vaccination in general practice are those Patients who are on the GP practice's registered patient list; are unregistered patients; or are care home workers or primary medical services workers which are registered on another primary medical services practice's list of patients, but who have been advised by the Commissioner (NHSE) that they may elect to receive the vaccination from the GP practice for convenience; and fall under the cohorts listed below: [] Please see paragraph 9.2 in the specification for the list of patient cohorts who will be prioritised for vaccination.	<ul> <li>This may be seen as suggesting that the patients of practices who have not signed up to deliver the ES will not have access to it.</li> <li>We have received previous assurance from the GPC that patients of non-participating practices <i>will</i> have access to the ES services either at mass vaccination sites through the national programme or other PCN Designated Sites, however this assurance does not appear in the specification document.</li> <li>At this point it is unclear what the commissioning arrangements will be for patients registered with practices who have decided not to sign up to this ES.</li> </ul>

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Paragraph in	What the specification says	What this means for practices and PCN groupings – LMC comments
the specification 9.2 cont.	<i>"Patients eligible to receive the vaccination in general</i>	
5.2 cont.	practice and the cohorts will change in line with the JCVI	
	authorised announced eligible Patients and cohorts. GP	
	practices are required to keep up to date with these criteria	
	which will change from time to time and will be notified by	
	NHS England of amendments through the Primary Care	
	Bulletin (as referred to in paragraph 10)".	
9.5.1	Practices must cooperate with national call/re-call systems	Details of the national call/re-call system have not been released yet,
	and in addition write, text or call patients as appropriate.	so it is not possible to anticipate the workload implications of this, in
	They must keep clear records of how they have contacted,	addition to making proactive contacts.
	called/re-called patients.	
	To support high uptake and minimise vaccine wastage,	
	practices are also required to proactively contact patients	
	for vaccinations in addition to call/recall requirements,	
	where appropriate to do so.	
	There is no requirement to call/recall Care Home residents	
	or Health & Social Care workers.	
9.5.4(a)	Informed patient consent must be obtained by a registered	It is the practice's responsibility to obtain informed consent from
	health care professional.	patients who wish to be vaccinated. Details of a national consenting
		process have not been released yet, so far there has only been
		reference to a national consent form, which has not been published
		yet either.
		It is also unclear how informed consent will be obtained from people
		with limited or no mental capacity.

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9.5.7	"Patients receive a complete course of the same vaccine, unless in exceptional circumstances in which, for a patient attending for a second vaccination, that first vaccine type is not available, or the vaccine type received is not known".	Mixing vaccine types between the two doses appears to be possible only in exceptional circumstances.
9.7	"The GP practice must ensure the Patient has understood that failure to receive all recommended doses of the vaccine may render the vaccination ineffective and should ensure that a follow up appointment to receive the subsequent	It is the practice's, not the patient's responsibility to ensure that the patient has understood the implications of not receiving the second dose.
	dose has been booked, acknowledging that in exceptional circumstances appointments may need to be moved, before administering the first dose of the vaccine".	The appointment for the second dose has to be booked before the first dose is administered.
9.8.1	This paragraph sets out the qualifications, experience and training requirements for healthcare professionals administering the vaccine.	
	Specific attention should be given to 9.8.1 (b), which stipulates that vaccinators must complete the relevant training modules on the E-learning For Health website.	<ul> <li>9.8.1(b) – the details of the e-modules are not available yet.</li> <li>The overall training requirements are quite onerous and the onus is on the vaccinators to ensure they meet them.</li> </ul>
	9.8.1(c) and 9.8.1(d) make reference to immunization, administration and anaphylaxis training as well.	GP practices are required to keep comprehensive records of all relevant training undertaken by staff involved in the delivery of the ES.
9.8.1(e)	"[Healthcare professionals must ensure] they have understood and be familiar with the Patient Group Direction for the COVID-19 vaccines, made available by Public Health England and authorised by the Commissioner (NHSE) including guidance on who can use them."	The Patient Group Direction for the Covid-19 vaccine is yet to be published.

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9.8.2(b)	All other persons involved with the delivery of the ES must be supervised by a healthcare professional.	
9.9	This paragraph sets out the requirements in terms of receipt, storage, preparation and transportation (cold chain) of the vaccines.	Practices must ensure that their vaccines fridges have a min and max temperature, readings are taken daily and appropriate measures are in place for when readings are out of the recommended range.
	Vaccine wastage must not exceed 5%.	It is unclear what the implications of exceeding 5% wastage would be for practices.
Monitoring and r	eporting	
10.1 and 10.2	Practices and their PCN groupings are required to monitor and report all activity information. Practices are also responsible for reporting adverse events and providing information to patients who may experience	The reporting standards have not been published yet, so it is not possible to anticipate the workload implications. The specification places a responsibility for aftercare on practices,
	adverse events after leaving the vaccination site. Practices to follow MHRA incident management processes in the event of a severe reaction.	which may generate additional workload if patients leaving the vaccination site contact the practice for further advice, or if they have concerns etc.
Payment and val		T
11.1	"A payment of £25.16 shall be payable to the GP practice on completion of the second administration of the vaccination to each Patient" "NHSE does not intend to make payment for the administration of a single vaccination, to encourage GP practices to ensure that Patients are called/re-called to second vaccination appointments and to reduce bureaucracy for practices.	As payment will be made after the second dose in most cases, there is a potential cashflow issue because of the time lapse between the two doses (21 days) and the impact of this on payments.

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11.1 cont.	Payment will however be available for single administration of the vaccination in exceptional circumstances as set out at paragraph 11.3"	
11.2	<ul> <li>In addition to 11.1, practices will be eligible for the £25.16 payment when <i>all</i> the following requirements have also been met: <ul> <li>patient was within the JCVI specified cohorts</li> <li>patient was vaccinated with the specific vaccine recommended by JCVI</li> <li>patient was vaccinated at a Designated Site as agreed by your PCN grouping</li> <li>the vaccination has been recorded properly</li> </ul> </li> <li>practice has not received payment for this vaccination from any other source apart from NHSE</li> </ul>	Practices must ensure they meet <i>all</i> these requirements in order to qualify for payment.
11.2.3	"GP practices must make arrangements within their PCN Grouping for the nomination of a host GP practice for the PCN Grouping which will receive payments due under this ES for and on behalf of the GP practice". "The host GP practice 2will then receive data which enables it to identify how many Patients on the GP practice's list of registered patients have been vaccinated, for verification and the transfer of funds to the GP practice".	<ul> <li>Each PCN grouping needs to nominate a host practice which will receive ES payments on behalf of all practices in that grouping.</li> <li>The host practice will distribute the funds accordingly once payment has been calculated for each practice based on the number of patients vaccinated.</li> <li>This is a new administrative process that host practices will have to put in place in order to enable the distribution of funds to other practices in their PCN grouping.</li> </ul>

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11.2.3 cont.		PCNs should help and support their host practices to implement this process and ensure it is appropriately described in their Vaccination Collaboration Agreement.
11.3	<ul> <li>This paragraph sets out the exceptional circumstances and criteria by which practices should be paid for a single dose of the vaccine and these include: <ul> <li>unsuitability of patient</li> <li>changed circumstances in relation to patient</li> </ul> </li> <li>vaccine was not provided to the practice in time for the second vaccination within the recommended timeframe</li> </ul>	<ul> <li>Please note:</li> <li>If the patient has definitely decided they do not wish to receive the second dose, this should be after a consultation with a clinician. This consultation must be appropriately recorded as evidence for payment.</li> <li>If the patient DNA'd their second vaccination appointment, the practice must ensure they have made at least two separate contacts with the patient within 60 days following the administration of the first dose. Again, these contact attempts need to be recorded.</li> <li>Apart from the administrative burden and the time that needs to be spent on the above, there are also likely to be delays in payment given the 60-day timeframe within which a practice needs to make two contact attempts with patients who DNA'd their second appointment.</li> </ul>
11.7	<i>"Practices may not claim payment for Patients vaccinated outside of the PCN grouping (for example, at a vaccination centre)"</i>	This appears to suggest that if a PCN grouping has selected a mass vaccination centre as their PCN Designated Site, practices will not be eligible for payment. This requires urgent clarification from NHSE/GPC.

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Paragraph in the specification	What the specification says	What this means for practices and PCN groupings – LMC comments
Withdrawal from	this ES	
12.1	Practices who wish to withdraw from this ES after signing up to it must give 42 days' notice to NHSE, unless NHSE agrees a different timescale.	This means that if a practice who signs up to the ES changes its mind and decides to withdraw immediately after, they will still be bound by the provisions of the ES and <i>will have to deliver it</i> for 42 days (6 weeks) before they can withdraw.
Variations to and	subsequent withdrawal from this ES	
13.1	Due to the continually evolving nature of the pandemic, resources, vaccines supply levels etc, this ES will need to be responsive and may be frequently updated.	
13.2	"Variations to this ES will be published on the <u>NHSE website</u> and will take effect immediately on publication. GP practices will also be notified of any changes via the Primary Care Bulletin (as referred to in paragraph 10)".	As variations to this ES will take effect <i>immediately</i> on publication, practices need to stay alert and keep themselves up to date with the changes by <u>signing up to NHSE's Primary Care Bulletin</u> . This means that even unilateral changes made by NHSE without consultation with the GPC (our comment on paragraph 1.2 refers) will
13.3	If the ES specification is changed, practices will be auto- enrolled in the new specification, unless giving notice under 13.4	still be enforceable and practices will be bound by them immediately.
13.4	Following variations to this ES, if practices are unable to meet the new requirements, they must withdraw from it by serving 42 days' written notice to NHSE and explaining the reasons for their withdrawal.	Following on from paragraph 13.2, practices who give notice to withdraw from the ES following variations to the specification, are still bound by the amended/varied terms of the ES during the notice period, which cannot be less than 42 days.

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Paragraph in the specification	What the specification says	What this means for practices and PCN groupings – LMC comments
13.4 cont.		It is really important to ensure that when a practice formally withdraws from the ES, the Vaccination Collaboration Agreement is amended accordingly to reflect this change, as otherwise the practice may still be bound by its terms even after withdrawal.

#### Summary

- You have until 23.59, Monday 7 December to make an informed decision as to whether to sign this contract and agree to be bound by its terms.
- Once signed, this contract becomes an extension of your core GMS contract (as with all national Enhanced Services).
- Once signed, you cannot exit the contract without giving 42 days' notice.
- Practices must consider signing this Enhanced Service on an individual basis. However, it must be delivered within a group of participating practices who together sign a Covid-19 Collaboration Agreement, which describes the way in which practices will work together to deliver services either at the Designated Site, or at care and residential homes.
- With joint agreement, this service might be partially or wholly subcontracted.
- The specification of this Enhanced Service cannot be altered locally, although it can be varied by NHSEI nationally. This may affect wastage, notice periods and payments to practices.
- Various accompanying documents remain unpublished or yet to be determined.
- CCGs can provide additional discretionary support.
- The Enhanced Service specification can be modified over time, and this is likely to relate to changes in vaccine characteristics and supplies, and manufacturers' data.

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Practices should decide whether or not to sign this Enhanced Service on the basis that this represents a commitment of practice capacity to deliver the Enhanced Service specification requirements; there is no requirement to sign and all practices' patients will be eligible to receive Covid-19 vaccine via the national programme, regardless of the individual practice decision. Colleagues should not feel coerced either way.

At Londonwide LMCs, our teams will continue to support all GP practices whether or not you decide to participate in this Enhanced Service.

Londonwide LMCs wish to thank Vicky Ferlia, our Director of GP Support services, for her amazing work in producing this guidance during such a pressurised and critical time. Our analysis reflects many points included in the guidance published by Berkshire, Buckinghamshire and Oxfordshire LMCs and Surrey and Sussex LMCs and we would like to acknowledge their contribution to this guidance.