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Northumberland Local
Medical Committee

Enhanced Service – COVID-19 Vaccination Programme

Summary of FAQs and updated documents

Issue 3 (15.12.2020)

Following on from the summary of FAQs we sent on Friday, NHS England has further published the following documents: **(Please note all amendments have been highlighted in red)**

- ❖ Covid-19 Enhanced Service (ES) Specification (version 2 updated sections 5.2 and 9.2)
- ❖ NHS England » COVID-19 vaccination programme 2020/21: COVID-19 Enhanced Service Vaccination Collaboration Agreement
- ❖ Coronavirus » Wave 1 mobilisation of the Primary Care COVID-19 Vaccination Programme 2020/21 - Letter from Dr Nikita Kanani, Ed Waller (england.nhs.uk)
- ❖ Coronavirus » Legal mechanisms for administration of the COVID-19 Vaccine(s) (england.nhs.uk)

These documents contain specific information that practices and PCN groupings need to be aware of when assessing whether they can deliver the ES, which formally begins on 08 December 2020.

Throughout the week, many of you will have been considering the content of these documents in readiness for confirming your decision before 23.59 on 07 December 2020.

Recognising that some of you will already feel ready to commit, we know that queries have been raised regarding certain elements of the specification and that the ask to sign up within such a pressing timeframe is a challenge.

We are issuing this updated summary of FAQs and updated documents compiled from local queries and also national ones that we hope can provide those practices and PCN groupings who need it with some clarity and reassurance, noting that this is a very fluid situation, and that updates and guidance are being updated on a daily basis.

This document has been produced in collaboration with Northumberland Local Medical Committee.

1. How does this relate to our core GP contract?

Contractually, signing up to deliver this enhanced service is no different to signing up to other enhanced services. The CVP ES will be commissioned under section 7a of the 2006 NHS Act, as an enhanced service directed by NHSEI, using full delegated powers from the secretary of state. This provides flexibility for necessary amendments to the specification to be made swiftly, by national agreement between NHSEI and GPCE only. This is crucial in such a fast-moving environment where we will need to add in new information without delay as more vaccines are supplied with different requirements.

2. If a practice declines to sign up to the ES now but changes their mind later after the deadline, can they sign up later after that date?

Yes, there are no guarantees for such practices, but it may be an option.

3. If a GP practice does not choose to sign up with the rest of their PCN how are their patients covered?

~~There is currently a lack of clarity about the mechanism that will be used to deliver the service for these patients, this is yet to be confirmed.~~

Paragraph 9.2 of the ES has been amended to clarify that patients from Practices that do not sign up can be vaccinated by other Practices.

4. When do we have to make a decision?

You have until 23:59 on 07 December to voluntarily accept or decline participation in the CVP ES from 07 December 2020 – 31 August 2021, with responses via an email to the CCG, with the name of the designated vaccination site included in the email.

5. Is there any way we can deliver this from our practice?

No. The designated single PCN site needs to have been agreed by the CCG.

Additional sites may be possible in the future, but this is not currently permissible under the CVP ES.

6. Where does the responsibility and liability sit?

PCNs don't exist in any legislature, so any responsibility and liability rests with member practices. Practices will be jointly and severally liable for the vaccine, its safe storage and delivery of this service with other PCN members and may want to seek legal advice over the creation of a Collaboration Agreement, which needs to be in place at least one day prior to the date of the first administration of the vaccines. You will be jointly liable, with your PCN member practices, for the programme, the stock of the vaccine, including any financial liability or costs incurred.

6a. What are the implications of using a PSD?

At present a PSD mechanism is being used. A PGD has not been issued yet. Although this is expected this week. The prescriber takes full accountability and responsibility for the patient and the members of staff administering the vaccine; unlike in a PGD or National Protocol where staff would be taking responsibility for their own tasks. [Coronavirus » Legal mechanisms for administration of the COVID-19 Vaccine\(s\) \(england.nhs.uk\)](https://www.england.nhs.uk/coronavirus/legal-mechanisms-for-administration-of-the-covid-19-vaccine/)

6b. What are the implications of the Collaborative agreement?

The Collaboration Agreement is a 34-page legal document which all participating practices are required to sign published late on Friday. The published template can be altered but must cover all areas listed in paragraph 6 of the ES.

A Collaboration Agreement is mandatory in that it must be signed as a requirement of taking up the ES. It has to be signed by all the collaborating Practices. Paragraph 4 makes it clear that this is a "legally binding contract", although how this would be pursued between the participating Practices is unclear. It is also recognised that the agreement will be updated, but whether this is by national direction or by mutual agreement between the practices is not clear.

The Agreement is quite specific in terms of the secondment arrangements between practices, whereby staff go from collaborating practices to work in the PCN designated Vaccination site. It is also specific in terms of the responsibilities and liabilities of the employing practice and the receiving practice. (The Host) Given the uncertainties around this new vaccine, the level of preparedness training of staff, Practices will need to consider whether they are comfortable in signing such undertakings. Ideally there should be time for these issues to be examined and debated within PCNs.

The indemnity arrangements are set out in clauses 34 - 40 and, again practices will need to consider if they are willing to accept these arrangements.

Clause 34 states: Each Collaborating Practice accepts unlimited liability for:

- a. death or personal injury caused by its own negligence; and
- b. fraud committed by it or on its behalf

Clause 38 states: The Collaborating Practices agree to indemnify and keep indemnified the Host Practice against all costs, claims, demands, liabilities and damages incurred or suffered by the Host Practice as a result of any act or omission of the Collaborating Practices, their employees or agents except in so far as such costs, claims, demands, liabilities or damages arise or are contributed to as a result of the Host Practice's (or the Host Practice's employee's or agent's) act or omission.

The Agreement also sets out an elaborate process for decision making and meetings which, given the pressures Practices are under, doesn't appear realistic and you should review this clause.

There is a Schedule that sets out the financial arrangements, but this says very little and leaves it to the PCN to sort out how money will flow between the collaborating practices.

6c. If we don't sign the ES, will we have to sign the collaborative agreement?

In order for your patients to receive the vaccine from the PCN grouping, you will need to sign the collaborative agreement regardless of whether or not you sign the ES. It would appear at the moment that patients would have to go to a mass vaccination site.

7. What can we do to mitigate the potential liabilities?

Nothing. Once signed, the CVP ES becomes an extension of your core GMS contract (as per all national enhanced services) if you do not meet the requirements, then any money already paid to you may be clawed back by direct deduction via Open Exeter. You may also be liable for the failure of your fellow practices to meet the requirements. It is solely down to Practices to make this decision, however, be aware that there is still further clarity and guidance which is not available at this time.

8. Will NHSEI have to seek agreement with GPC England if they wish to change the CVP ES?

No. NHSEI may unilaterally impose variations or additions, they do not need to consult with GPC England. If changes or variations are made, you must fulfil those requirements. You may be enlisted to support other practices outside of your PCN grouping.

9. Can we serve notice if the CVP ES is changed?

Once signed, you cannot exit the contract without serving 42 days' written notice to NHSEI, with supporting reasons unless otherwise agreed with the commissioner (NHSEI). If unilateral variations are imposed to the CVP ES, you will have to abide by them for the full notice period. You will still be bound by the Collaboration Agreement and remain jointly and severally liable for the duration of the CVP ES unless the Collaboration Agreement is amended.

10. Who will undertake consent?

It is the practice's responsibility to seek informed consent, that needs to be obtained by a registered healthcare professional. There is no mention of a nationally coordinated consent system. However, it has been confirmed there is comprehensive cover from the Clinical Negligence Scheme for General Practice.

Under the current arrangements where a PGD is not available administering the vaccine will be through a PSD, there is clear guidance available as to the consent process. [Coronavirus » Legal mechanisms for administration of the COVID-19 Vaccine\(s\) \(england.nhs.uk\)](https://www.england.nhs.uk/coronavirus/legal-mechanisms-for-administration-of-the-covid-19-vaccine/)

In addition to this the e-LfH modules are a good guide to the consent process. There is an onus on Practices to make sure their staff are appropriately trained – see section 9.8 of ES.

11. What happens in the exceptional circumstances where we can't deliver a follow-up dose?

Exceptional circumstances where a practice may be paid for a single vaccine, include: adverse events following the initial dose; end of life care being commenced; death; a consultation recorded in the record with a clinician when a patient declines; the patient DNAs despite two separate attempts to contact and 60 days elapsing. It is extremely important that practices keep accurate records to facilitate correct payment.

12. When does this actually start?

Designated sites will be given 10 days notice of the first vaccines becoming available to ensure sites can be stood-up and clinics arranged. Practices and their PCNs must register with the Primary Care Bulletin as outlined in the NHSEI documentation, as this will be the CVP ES communication channel. On 03 December it was announced that 280 GP sites will be asked to commence the week commencing 14 December. Events are moving quickly, and all this is subject to change daily.

13. Will we have to be open 8am-8pm seven days a week?

The CVP ES states that the PCN site must be able to deliver the vaccine 8am-8pm seven days a week, including bank holidays, where NHSEI inform the PCN that this is required. This is in order to maximise the number of vaccinations and minimise waste. Wastage must not exceed 5%. There is no clarity as to the consequences of a wastage level >5%. There is also no clarity as to how you are to be expected to guarantee the connectivity of your broadband. Remember, the ES also requires you to ensure designated site security at all times.

14. Who will be eligible?

Patients are to be vaccinated in strict order of cohorts. Please reference 9.2 of the CVP ES. 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. At the time of writing (7 December 2020), call and re call arrangements are still under discussion. As national PGDs has not been released vaccination will need to take place under a PSD.

15. What do we do with anti-vaccination protesters letters?

Any correspondence from anti-vaccination protesters should be sent to either the CFVG or NHSE/I

16. What if there isn't enough vaccine for the over 80s cohort to begin with?

The current advice is for the PCN/GP practices, as they know their own patients, to decide who should receive the vaccine to begin with.

As your representative body the LMCs feel very uncomfortable with the current situation. It would appear that Practices are being asked to make an (almost) irreversible commitment without having all the facts at their fingertips. They are being asked to sign the ES specification by 11.59 tonight yet there has been little time to consider the legal implications of the specification, its responsibilities and liabilities. The details of the collaboration agreement and its relationship to the PCN schedules, the significant operational implications and prescribing liabilities contained within the PSD/ PGD are such that the LMCs feel unable to give assurance about signing up to this ES. However, we trust that the situation will become clearer over the next few days. In the meantime, if you feel you need to sign up, you will be doing so in good faith.

The LMC will support practices and PCN groupings, irrespective of what decision you make.

We will continue to liaise with NHSEI, CCGs, ICS and BMA GPC colleagues to provide you with much needed advice and guidance during these challenging times.