7th December 2020

Dear Colleague

The information here is current as of 5th December 2020.

Updates and recent releases are here:

https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/primary-care-guidance/
4th and 5 December updates include – Legal Mechanisms for the administration of the COVID-19 vaccination, Wave 1 Mobilisation 2020/21, Collaboration Agreement, Update to enhanced specification to include MHRA information.

Public Health England has published guidance for healthcare professionals who will deliver the COVID-19 vaccine which includes information about the vaccines (as they become available), vaccine recommendations and eligibility, contraindications and precautions, and vaccine administration issues.

PHE has also published a new COVID-19 chapter in the Green Book which has guidance on the vaccine, provisional priority groups, advice on high risk groups and on potential adverse effects, which current evidence suggests are mild and short-term.

The BMA **guidance page about the COVID-19 vaccination programme** has been updated and has FAQs throughout to answer questions from practices. This continues to updated regularly, as and when new information becomes available.

Specific updates to the COVID vaccination specification since release are:

Amendment to say GP practices need to work together as a joint enterprise and the patients who attend for COVID-19 vaccinations will attend what is deemed as a temporary single medical practice for the purpose of regulation 3(8)(b) of the Human Medicines Regulations 2012.

There has been an addition to 9.2 to make it clear that registered patients of non participating practices can be vaccinated by the practice group. It has also been updated as per the JCVI recommendations. This includes an addition at the end of that paragraph about flexibility of vaccine deployment to minimise wastage with due attention to mitigating health inequalities, vaccine administration constraints, exceptional individual circumstances and availability of suitable vaccine.

Wave 1 – on Monday 7th December NHSEI will be writing to practices in Wave 1 who are required to start delivering the vaccine to patients from 14th December. They will have consumables, IT equipment and fridges etc delivered. Access to training will be provided and log in for the Foundary IT system. The NHSEI letter states ‘While urgent care will need to continue to be provided across general practice, for the days on which vaccine is being delivered from these sites, this programme will be the top priority’. You may wish to consider RCGP's advice regarding workload prioritisation as part of your planning process.

There is a useful suite of documents at the end of the Legal Mechanisms for the administration of the COVID-19 vaccination which includes a template patient assessment form, patient specific direction and suggested staffing/flow mechanisms.

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.

Is there any way we can deliver this at individual practice level?

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.

If this is at a PCN level, does the responsibility and liability sit with the PCN?

No. 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 will need to use the Collaboration Agreement, which has been approved by the BMA, this 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.

PCNs can adapt the collaboration agreement, it must contain a number of specific provisions including, but not limited to, lead contact details for the PCN; GDPR and record-sharing; financial processes, reporting arrangements and stock taking; subcontracting agreements; pan-PCN staff sharing arrangements (not covered by ARRS); patient communication protocols and call/recall; compliance with mandatory national systems and designated site details.

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.

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. If you fail to, then you may not be paid for work already done. You may be enlisted to support other practices outside of your PCN grouping. We were surprised to note the inclusion of "Ministers" as a group who can make unilateral alterations to the CVP ES.

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. 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. The post-payment verification process will be run by NHSEI, not the CCG. NHSEI may audit practices. You also have to book the second dose before giving the first, which will complicate matters. We recommend you do not sign up to the CVP ES if you intend to serve notice before 31 August 2021.

When does this actually start?

Wave 1 sites start on 14th December and practices involved at this stage will be contacted and advised of vaccine delivery dates. 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. Sites not in Wave 1 will be given 10 days notice. 50 acute trust vaccination sites have been told to prepare to deliver the Pfizer vaccine to mobile >80 year olds from next week. Events are moving quickly, and they are uncertain. All this is subject to change on a daily basis.

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. The GPC have been assured we will not have to work Christmas, however, contractually this could happen and as this is a fast moving picture there are no guarantees. Wastage must not exceed 5%. There is no clarity as to the consequences of a wastage level >5%. You must also be able to guarantee the quality and connectivity of the broadband, and you are responsible for the security at the designated site, at all times. This could prove expensive.

Who will be eligible?

All patients are eligible – patients registered at other sites; care home workers resident outside the PCN; unregistered patients – but only in the strict order of cohorts agreed by Government. These have been published by the JCVI, but with this afternoon's news of hospital sites and >80s being an example, it is clear that much of these details are subject to change. It is as yet unclear how the payment mechanisms for these patients will work. Naturally, practices signing up will do all they can to facilitate and co-operate with the need for national call/recall requirements and record keeping – but the systems required to be set up and in place to meet these requirements are unclear at this stage (provisionally we are advised they are the systems as described in our last bulletin). As it stands today we do not have a Patient Group Direction (PGD) and one may not be forthcoming before 11th December 2020. Until such time as the national PGD is written practices will have to use a Patient Specific Direction (PSD), this will significantly slow down the flow of patients.

The use of a PSD to support vaccine delivery is not a long-term viable solution due to the following reasons:

a) Prescribers need to be medical practitioners, Independent nurse or pharmacist prescribers (who are suitably trained with experience in immunisation) limiting the number of staff who can prescribe.
b) A Prescriber will need to give an authorised instruction to administer a medicine to a list of individually named patients where each patient on the list has been individually assessed by that prescriber. The prescriber must have adequate knowledge of the patient's health and be satisfied that the medicine to be administered serves the individual needs of each patient on that list.

c) There is no restriction in law as to who can administer the medicine to the patient, under a PSD however the prescriber has a duty of care and is professionally and legally accountable for the care, he/she provides, including tasks delegated to others. Therefore, the prescriber must be satisfied that the person to whom practice is delegated has the qualifications, experience, knowledge and skills to provide the care or treatment involved. In other words you are going to want to use your own staff to administer. A national protocol and PGD are being developed but it is not there yet.

In order to use the doses of the vaccine in 3.5 days and minimise wastage each site is going to have to achieve a vaccination rate of 312 per day when dealing with the Pfeizer vaccine. The clinical assessment and consent process must be undertaken by a registered healthcare professional. Oversight of administration and liability lies with the prescriber.

It must be noted that in order to be able to issue a patient specific direction the prescriber must have sufficient information on the vaccine to enable them to confidently write the instruction and 'prescribe' the vaccine for each individual patient. This requires sufficient time for them to familiarise themselves with the contents of healthcare professional fact sheet once published (SPC equivalent under the 174 regulation for temporary authorisation of the vaccine) and the updated chapter in the Green Book and / the e-learning module if available. The vaccine whilst authorised is still not fully licensed. Therefore, the types of prescribers that can issue a patient specific direction for the vaccine are medical doctors and independent nurse or pharmacist prescribers only.

A useful summary of the Pfizer vaccine from a Webinar held by our Wessex LMC colleagues is here: https://youtu.be/IFE8o9DIm9s

The models in appendix A of the NHSE document describe two prescribers per vaccination clinic (working for 8-12 hours to get the 312 patients through), this could pose significant business continuity issues given that practices will still be expected to deliver the GMS contract. There are hints that we may be able to adapt our work in the statement that the immunisation programme takes priority.

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. There is no guidance or clarity around obtaining consent for those with limited or no capacity at the time of writing. However, there is comprehensive cover from the Clinical Negligence Scheme for General Practice. This cover is extended to non-registered patients and all persons delivering care under the CVP ES.

In terms of cashflow, when could we realistically expect to receive our first payment?

£25.16 will be paid on completion of the final dose. This will present a significant cashflow concern. The first monies are likely to come at the end of January, assuming that payments will be made on a monthly basis. You will only receive payment if your patient is within the required cohort; has been vaccinated by your PCN at the designated site; has been vaccinated with the correct vaccine and that the vaccination has been properly recorded. NHSEI state they will take action to ensure appropriate cashflow, but there is currently no detail on the mechanism or level of funding that may support this. Practices must not receive any other additional funds from any source aside from NHSEI. If a local CCG wished to 'top up' the CVP ES, they would be prohibited from doing so. One lead PCN practice will receive all the payments and be tasked with distributing them accordingly.

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. The 60 days will add to the cashflow implications of necessary administration. If a practice fails to keep sufficient records, they may not receive payment. Practices cannot claim for patients who receive their vaccinations at a separate vaccination centre (e.g., another PCN, trust, or mass vaccination site).

Can we subcontract delivery of certain cohorts?

Yes, this is permissible, but the tight financial envelope means this is unclear how that would be financially possible. Practices have asked us if the Federations could play a role. What is clear is that capacity is an issue for them as much as it is our practices. They are going live with the COVID

Virtual Wards, delivering the usual work they are committed to; and supporting the extended access hub arrangements.

Will KCHFT be able to do housebound patients?

At the time of writing this is unclear. Kent LMC are pressing for clarification as soon as possible. The guidance stipulates a 'locally agreed solution'. The CCG is very aware of the make/break issue around our capacity and ability to deliver to housebound patients.

Will data be entered using System 1/Vision/EMIS?

No. As previously advised there are national systems which are being worked on to collect vaccination data. There is a hope that in time a system compatible with GP systems will come online. The vaccination event data will be recorded on the Pinnacle system. Training and user guides are 'in process'. The Pinnacle system will also automate payment to a nominated practice. Practices will not be able to use the National Booking System. We don't know how a local call/recall system will fit with the national call/recall system.

What Can We Do?

We are awaiting a local update on housebound patients, however we want to get a safe vaccine into our patients, as soon and as safely as possible. Like them, we and our practice teams want to return to normality, and be part of that journey of recovery. We recognise that for the majority of our vulnerable patients, they will prefer to receive a vaccine closer to home, somewhere they know, from a team they trust – their GP practice. However, there is an expectation on general practice to achieve the impossible here: continue business as usual; vaccinate all 50 to 64 year olds against flu; prioritise our most vulnerable patients; manage the work transfer from trusts and the ongoing needs of those waiting for interventions and diagnostics. We cannot change the CVP ES. We voluntarily accept it… or we decline it.. Local PCN/workforce perspective: You may feel you have enough additional roles to support in delivery of the COVID vaccination programme. Many areas in Kent and Medway however are under doctored and under pressure. While the CCG and KCHFT are recruiting and gathering details of potential staff there is no firm mechanism or guarantee that there will be additional staff available to assist with the primary care delivery. Your practice should assume that they will not be supplied with additional workforce and will be responsible for recruiting and training additional staff if needed.

What if my practice does not sign up to the Enhanced Service?

The lead provider of the mass vaccination programme for our area (KCHFT) would be tasked with the delivery of whatever a PCN declined. We are not aware of anything that would prohibit KCHFT from itself entering into a subcontracting agreement with general practice, either at a PCN or practice level. This would not remove the work, we know that, but it would significantly alleviate concerns that the delivery would be cost neutral for practices and limit the liability to member practices. Let us be clear, no one will make a profit from the Covid vaccination programme. We firmly believe our practices should not make a loss and will continue conversations with the CCG. KCHFT may not have the capacity or appetite to enter such an arrangement.

This proposal could also open up other opportunities. In the coming weeks it is highly likely we will see the MHRA approve the AstraZeneca vaccine that could be delivered at a practice level, more in line with a delivery akin to the flu vaccination schedule in the out of hospital setting, time will be needed to get the PGD in place. We know the CCG are as equally committed to finding a safe solution to delivering the COVID vaccine to our patients as we are. As your LMC, we want you to be able to partake in this effort as much as possible. The CVP ES decision is a practice decision, not that of a PCN, but of course we encourage you to discuss your position as soon as you can with your clinical director(s). You need to be mindful of all available information, contractual documents and requirements before making an informed decision. You need to be fully aware that if you sign the CVP ES, you are signing a contract which may be unilaterally amended at will by

NHSEI, and you need to take this into consideration when making your decision. You have contacted us with your concerns over the past week. We too are worried, the ask of general practice and our community and acute colleagues is huge. Whilst we cannot recommend the CVP ES to you, we will support all practices, irrespective of what decision you make. We are available to answer individual colleagues questions via info@kentlmc.org, or feel free to telephone the office.

Kind regards

The Kent Local Medical Committee

With thanks to our colleagues at Cambridge LMC, Kent LMC have adapted and updated their original document.