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To: Phase 3 PCN LVS sites

CC: Regional Directors of Commissioning

Regional Directors of Primary Care and Public Health

CCG Accountable Officers

ICS leads

11 October 2021

Dear colleagues

Use of Moderna (SpikeVax®) COVID-19 vaccine in PCN-led vaccination sites

We can confirm that supply of Moderna vaccine, previously deployed to Vaccination Centres and Community Pharmacy sites, is now expanding to PCN sites to support the delivery of booster vaccinations.

This note outlines the process for assuring PCN sites to use the Moderna vaccine safely and effectively; and applies to any new sites (not just PCNs) which have not previously been assured for this vaccine. The process is to be owned by regional teams, working with their local systems, who will be in touch with sites about taking on Moderna vaccine, subject to meeting the assurance checks.

The first date that PCN sites would be able to record the administration of a Moderna booster dose is 15 October 2021, subject to completion of the assurance process. The assurance process should be completed by regional teams in conjunction with sites and systems.

It will not be possible to allocate the Moderna vaccine to all PCN-led vaccination sites and so regions should liaise with vaccination site leads before sites prepare to receive the vaccine. Any site which receives confirmation from their regional team that they will be supplied the Moderna vaccine must take steps as outlined below to ensure that they are adequately prepared for rapid, safe and effective deployment.

Please note that an updated Patient Group Direction for Spikevax (formerly COVID-19 Vaccine Moderna) is now available here, alongside the updated National Protocol here.

1. Guidance

Information about vaccine characteristics for Moderna COVID-19 vaccine can be viewed in Chapter 14a in the Green Book and the Summary of Product Characteristics (SmPC). Guidance on boosters from JCVI outlines the appropriate doses for Moderna[1].

The Specialist Pharmacy Service (SPS) has prepared information relating to the use of COVID-19 vaccines. This includes advice on how to reduce the risk of errors where multiple

[1] https://www.gov.uk/government/publications/jcvi-statement-september-2021-covid-19-booster-vaccine-programme-for-winter-2021-to-2022/jcvi-statement-regarding-a-covid-19-booster-vaccine-programme-for-winter-2021-to-2022

vaccine types are available. It is possible to use more than one vaccine on a site where the safe principles for practice are implemented and risk of errors have been considered and mitigated. **Due to the risk associated with different** dosing, the storage, preparation and administration of Moderna booster doses should be separated in different cubicles to Moderna primary course doses. Primary courses include the third dose for immunosuppressed patients.

PCN sites can find information relating to the operational aspects of running a PCN LVS site in the mobilisation guide that was sent to you when your site was approved. It includes information on who to contact to get help on various aspects of the programme.

2. Staff training

Relevant staff who are rostered to work at these sites must complete the PHE Moderna e-learning module and assessment in advance of the sites going live with supply – the e-learning should only take 30 minutes to complete and 15 minutes for the assessment. They will also need to complete training on booster doses (covering half dose Moderna).

These staff will additionally need to be assessed and signed-off as competent in using the Moderna vaccine against the revised PHE COVID-19 Vaccinator competency assessment tool. Staff who are not rostered to work in any of the identified sites receiving supply of Moderna do not need to complete the e-learning at this time.

3. Site readiness

Site leads should ensure that all preparations are made to receive, handle and administer the Moderna vaccine. Sites who have previously received or are expecting to receive other brands should be prepared to mitigate the risks associated with handling multiple vaccines or different doses of the same vaccine on the same site per the site designation criteria.

We have produced a checklist to be used by PCN LVS sites to assess their readiness to receive the Moderna vaccine (see Annex A). The Clinical and Operational Site Leads remain responsible for ensuring that overall governance, systems and processes are safe. NHS England and NHS Improvement regional teams will need to be assured by systems that the actions within the checklist have been completed before delivery of vaccine is made. While the national team does not require a return of the checklist completed by each site, we will require confirmation from regional teams as to which sites have completed the assurance process so the allocations model can be updated. A list of Phase 3 sites will be shared with regional colleagues along with details of where to return when completed. There is no deadline for the assurance process to be completed; regions can assure sites as needed to reflect their supply planning, however assurance must be completed before the site goes live with Moderna.

Supply of vaccine will be dependent on this assurance, so you must not invite eligible patients to Moderna appointments until you have had specific confirmation from your regional team that you can do so. Supply of Moderna vaccine via Mutual Aid is subject to the same exceptional circumstances which apply to other vaccines. The restrictions are listed in the Mutual Aid Policy. The Roving model SOP outlines what is possible in terms of movement of vaccine.

4. Ordering vaccine supply

The option for sites to order Moderna boosters will not appear in plans until the national team has been informed that they have been locally assured to do so.

Assured PCN sites can order Moderna boosters in the same way that Pfizer is ordered currently, through the Supply Planner and Ordering Platform tools in Foundry. Supply plans are currently open for Moderna, with deliveries of booster Moderna available from Wednesday 13 October at the earliest. As supply plans are completed in advance, sites might find that they have a max cap of zero in plans that were created before the site was assured for Moderna. Sites can request an increase in these caps through the usual process in the Supply Planner.

Sites should be aware that:

- Quantities on the tool will be measured in doses to be administered or 'vaccination events':
    - The tool will take sites' inputs in either their Phase 2 or Phase 3 supply plans and translate that into the correct number of boxes of Moderna required at each site.
    - Minimum order quantities for Moderna will be 1 pack of 10 vials. For boosters, this will therefore be 200 doses (to accommodate half doses), whilst for first / second doses this will remain at 100 doses.

- There is the possibility that certain sites may not be able to draw a full 20 booster doses from a Moderna vial, depending on the technique used. As such, we recommend sites consider that they may need to receive up to 10% more vaccine than they expect when estimating the number of booster doses required.

5. Vaccine deliveries

Moderna vaccine will be delivered in a thawed state to approved PCN sites and will have a completed thaw label attached to the pack along with a new expiry date. Once delivered, vaccine must be stored at 2-8 degrees Celsius. Vials should be removed from the fridge 15 minutes before use and will have up to 30 days expiry at 2-8 degrees Celsius.

Your regional team will work with you to determine an appropriate volume of vaccine that can safely be administered by your site. If there are any exceptional circumstances in which you require further support or are worried that you will not be able to take delivery of your vaccine as set out, please speak to your regional team as soon as possible.

Vaccine deliveries will be made between 08.00 and 18.30 Monday to Friday. An estimated delivery window for the arrival of your vaccine will be emailed to you the day before your vaccine is due to arrive – usually by lunchtime. This provides you with a 2.5 hour estimated delivery window. Colleagues should be on site at the start of the delivery window to receive vaccine and to prevent delays to the remainder of the transport plan. To facilitate smooth delivery of the vaccine to your site, please ensure that your named, registered Health Care Professional (HCP) who will receive the vaccine is there on the day.

Your vaccine will be accompanied by consumables that may be delivered separately, but on the same day. Sites should plan to start vaccinating patients from the day after your scheduled vaccine delivery date.

6. Prevention of vaccine wastage

Sites must make all reasonable endeavours to avoid vaccine waste. Vaccination teams should be prepared to contact patients within eligible cohorts to ensure that all vaccine doses can be used.

7. National Booking Service

For those PCN sites using the National Booking Service (NBS), Moderna calendars are not automatically set up on Q-Flow. Your calendar will be made live as soon as possible and within 4 days from your allocation schedule being shared.

For sites who have not yet received a supply of vaccine: You will need to start using the NBS so that eligible individuals can book a coronavirus vaccination at your vaccination site.

For sites who have already started administering vaccinations: Setting up calendars for more than one vaccine type needs to be considered carefully. Guidance has been produced to support you. For further support, please visit the FutureNHS Collaboration Platform where you will be able to find:

i. in the Training Calendar, a link to drop-in sessions
ii. a recording of a previous webinar.

8. Workforce

Sites should review the need for additional workforce to support their clinic. PCN LVS sites have access to trained vaccinators through National Workforce Supply Routes. Volunteers for stewarding, signposting and check-in support from the Royal Voluntary Service can be requested directly through the GoodSAM app.

9. Finance

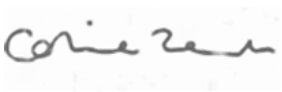
If additional equipment or costs are anticipated as a result of preparations for using the Moderna vaccine, then these must be agreed and approved by your Regional Team before any expense is incurred. Claims will be made in the same way as initial start-up costs.

10. Accurate records

It is particularly important that the correct dose is recorded against administration of booster vaccinations. To assist with accurate allocations, payment, and to reduce the risk of clinical errors, it is important that all vaccine events are recorded in the Point of Care system on the day of vaccination.

All sites must also complete the weekly stocktake web form to record their stock position and record any wastage. Each site is asked to complete the web form on a Monday morning to reflect stock held at close of day on the Sunday preceding and recording wastage during the previous 7 days. This will help ensure all future allocations are based on the correct data.

Many thanks for your continued commitment to the COVID-19 Vaccination Programme.



Caroline Temmink
Director of Primary Care Vaccinations
NHS England and NHS Improvement

Annex A: Moderna readiness checklist

Moderna readiness checklist To be completed where an additional vaccine brand is being introduced into a vaccination site.	Comments	Assured (Yes / No)
Have sites reviewed and implemented the SPS guidance on handling multiple vaccines including: • Lead Pharmacist oversight into the process • Clear separation of vaccine sessions by either time (separate sessions) or space (separate area) and a plan to reduce risk of errors and the wrong vaccine being administered. • Safety huddles, vaccine posters, different colour trays and stickers for different vaccines and extra marshals to support better queue management and ensuring patients don't re-enter the wrong queue. • Good front end triage and site level planning is required to manage the complexity of patient cohorts and ensuring vaccines are separated so the correct vaccine and correct dose is given. Patient flow should be tested, and a risk assessment completed, and mitigations put in place and signed off by the clinical lead.		
Have staff: • completed the relevant e-learning and training • read the updated chapter of the Green Book • been alerted to the importance of accurately recording the relevant dose of vaccine?		
• Are non-registered vaccinators competent in drawing up a half dose of Moderna?		
• Is there adequate space in the fridge to allow separation of each vaccine, eg are different vaccines physically segregated during storge, from receipt to administration?		
• Are the approved policies in place to support the receipt (including when frozen if applicable), storage, preparation, and administration of the vaccine? This includes good cold chain management for each vaccine being administered.		
• Is there a legal mechanism for supply and administration of the vaccine, eg the national protocol, PGD or is a patient specific direction in place?		

Name (Contractor)…… **Date ……..……**

Name (NHS England & NHS Improvement Regional Team) …… **Date ……..……**