Regional Clinical Advice Response Service 09/07/21

For any COVID-19 vaccination related queries or to escalate an incident please contact: england.swcovid19-cars@nhs.net

Please note that going forward and in line with the RVOC and NVOC, RCARS will now operate between the hours of 8am and 6pm over the weekend.

PLEASE SHARE WITH ALL RELEVANT STAFF INVOLVED WITH THE VACCINATION PROGRAMME

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COVID-19 Vaccination Autumn / Winter (Phase 3) planning

Letter – C3127

Dear colleagues

We communicated earlier in the year that local systems would likely need to prepare for the possibility of a COVID-19 vaccine booster campaign in the autumn or winter. Over the past few months, we have been working with regions and systems to learn lessons from Phases 1 and 2 and we have used these to inform the basic principles set out below for Phase 3, which

are designed to support your planning locally.

The Joint Committee on Vaccination and Immunisation have now published their interim guidance on booster vaccinations which states:

'JCVI advises that any potential booster programme should begin in September 2021, in order to maximise protection in those who are most vulnerable to serious COVID-19 ahead of the winter months. Influenza vaccines are also delivered in autumn, and JCVI considers that, where possible, a synergistic approach to the delivery of COVID-19 and influenza vaccination could support delivery and maximise uptake of both vaccines.

Any potential COVID-19 booster programme should be offered in two stages:

***Stage 1.** The following persons should be offered a third dose COVID-19 booster vaccine and the annual influenza vaccine, as soon as possible from September 2021:*
• adults aged 16 years and over who are immunosuppressed;
• those living in residential care homes for older adults;

• all adults aged 70 years or over;
• adults aged 16 years and over who are considered clinically extremely vulnerable;
• frontline health and social care workers.

***Stage 2.** The following persons should be offered a third dose COVID-19 booster vaccine as soon as practicable after Stage 1, with equal emphasis on deployment of the influenza vaccine where eligible:*
• all adults aged 50 years and over
• adults aged 16 – 49 years who are in an influenza or COVID-19 at-risk group. (please refer to the Green Book for details of at-risk groups)
• adult household contacts of immunosuppressed individuals'

We still expect readouts from several clinical trials over the course of the summer and, therefore, plans will need to flex as new information becomes available.

Therefore, the core planning scenario systems should prepare for is to **deliver booster doses of COVID-19 vaccine to the individuals outlined in the JCVI interim guidance above between 6 September and 17 December 2021 (15 weeks), as quickly and safely as possible in two stages using supply available to us over that period**. The JCVI have advised adults who are severely immunosuppressed should be offered COVID-19 boosters at the start of the booster campaign. Alongside this, local systems will need to deliver existing requirements for the flu programme (co-administered in a single appointment where supply and eligibility of cohorts align), continue to deliver routine vaccination programmes for children and for adults, maintain an "evergreen" offer to all adults who have not yet taken up the earlier offer of a first dose of COVID vaccination, and complete any second doses not yet delivered.

We are working with systems to pilot a 'make every contact count' approach to winter vaccination. This means building in the offer – where practical and appropriate – for those attending vaccination clinics to also have other health checks, such as blood pressure or atrial fibrillation checks.

1. **Delivery model**: So far, the COVID-19 vaccination programme has in weeks where vaccine supply has permitted, delivered a maximum of around 3.5m vaccine appointments per week. Phase 1 was predominantly delivered through general practice

and Phase 2 has seen increased participation from community pharmacy and increasing contribution from vaccination centres, as well as the popular convenience of pop-ups, walk in and roving models. This mix of delivery models, with tailoring to local community needs in partnership with local authorities, has played a critical role in reaching underserved communities. We are thankful for the efforts of all those involved and are conscious of the pressures being faced which will inevitably continue into autumn / winter. To build on the strengths of Phase 1 and 2, and ensure Phase 3 is delivered sustainably, we therefore recommend systems should deploy delivery models which:

i. **spread capacity across community pharmacy, vaccination centres and general practice.** Although general practice delivered the majority of vaccines in phase 1, spreading capacity across all delivery models will provide resilience and ease pressure on other services and workforces. For most areas it may be hard for general practice to deliver more than around 75% of vaccinations, based on learnings from Phase 1. In the majority of cases, local systems should therefore prudently plan for a minimum of 40% of COVID-19 booster vaccination through general practice and a maximum of 75%, drawing on the expertise of Local Authorities and subject to any agreement with local PCNs. Recognising their contribution in Phases 1 and 2**,** we intend to add an additional 1000 community pharmacy sites in the run up to September to support Phase 3 delivery, subject to interest and system need. Please note the capacity required to deliver 3.5m vaccinations a week consistently over this period and ensure that your delivery mix can support that.

ii. **consider the best delivery access for your population requirements**, making the most of community pharmacy**,** pop ups, mobile units and other approaches. Convenience builds uptake through ease of access via locations as well as opening hours. In doing this, systems should identify from the start how to maximise uptake of the vaccine in underserved communities, building on learning in Phases 1 and 2.

We intend to publish the general practice and community pharmacy service specifications for Phase 3 in the first part of July with a view to confirming those who would like to opt in in mid to late July. Existing delivery models, including through PCN groupings, will continue to play a vital role in COVID-19 vaccine delivery due to supply considerations.

2. **Workforce**: We recognise the need to ensure sufficient workforce is in place to deliver Phase 3 alongside the national flu vaccination programme and the continuation of routine immunisation programmes. Therefore, as in Phases 1 and 2, **we expect providers will be able to access centrally sourced workforce for Phase 3, including non-registered trained vaccinators through the lead employer model, using the national protocol as appropriate and national agreements with volunteering organisations**. Providers should seek to maximise the use of volunteers wherever possible. Workforce and training guidance for phase three will be released shortly and we ask systems to continue to tell us if there is more we can do to help.

3. **Estates**: Phases 1 and 2 have made use of a mix of commercial, NHS and other public sector and community estates to meet population requirements. Many commercial estates used in Phases 1 and 2 are now returning to their business as usual function, and therefore **systems should plan to maximise existing NHS estate use or commissioned provider premises, while recognising that in some cases commercial estate will remain the best value for money solution**. Regions and systems will be offered the flexibility to retain commercial estates into Phase 3, where there are demonstrable benefits for coverage, access and uptake amongst underserved

communities and where there is evidenced value for money in leasing arrangements. The following prioritised principles will apply to the Estates strategy from 1 September 2021 onwards:

i. Maximise use of existing NHS estate and commissioned provider premises first, including uptake of vacant available estate across England. This will include the use of Community Pharmacies and GP Surgery premises as well as property held by the NHS Property Companies, and where viable, Secondary Care and Mental Health estate. This may require additional planning and onboarding of sites to ensure that capacity needs can be met from a larger number of smaller premises.
ii. Use available Local Authority estate to backfill gaps in NHS coverage.
iii. Use private / commercial estate where required to target gaps in coverage, meet specific capacity shortfalls, or to better target underserved groups / cohorts.

4. **Vaccinating healthcare and social care workers**: As in Phase 1, we are expecting trusts to lead on vaccinating their staff with COVID-19 boosters through Hospital Hubs, as well as supporting the delivery of vaccinations to primary and social care staff as needed in the local system. The Government is shortly to consult on mandatory COVID-19 vaccination for all patient facing health and care staff.

5. **Changes to national processes and Phase 3 constraints**: System and regional engagement over the past few months has identified challenges and requirements for phase 3. We are taking the following actions to address these:

i. **Move to a "capped pull" ordering model** to support sites to have visibility and influence over the supply of COVID-19 vaccine. This will also allow sites to align COVID-19 vaccine with their flu vaccine supply for joint clinics to support co-administration, where timing of cohort phasing and eligibility of the programmes align.
ii. **Onboard additional primary care sites**. We anticipate being able to onboard additional community pharmacy sites in the run up to September. These will provide reach into underserved communities, increase weekend and evening vaccination capacity, and ease workforce pressures across primary care teams.
iii. **Work towards an infrastructure that enables point of care recording of both a co-administered and individual vaccination event,** recognising that this is likely to roll out across platforms as phase 3 progresses.

6. **Co-administration:** The JCVI have advised that 'early evidence on the concomitant administration of COVID-19 and influenza vaccines used in the UK supports the delivery of both vaccines where appropriate'. Co-administering flu and COVID-19 vaccines in the same appointment will allow more efficient use of resources and a better service for patients, as well as potentially helping to improve uptake of both vaccines. This will only be possible once the final results of the relevant clinical trials are published (expected later this summer), and where supply, regulation, and alignment of cohorts allows, particularly in primary care. If the ongoing clinical study finds that co-administration is safe and effective, **we intend to optimise for full co-administration of flu and COVID-19 vaccines in Trusts, residential care homes, to housebound patients and in other residential settings**. **We will actively enable and encourage co-administration in all other settings where possible (Local Vaccination Sites (LVS) and Vaccination Centres (VC))** by seeking flexibility to pool flu vaccine between practices, adding additional CP sites that can deliver flu vaccination to the COVID-19 vaccine supply network, and providing a tech and data infrastructure that is interoperable between the two programmes.

7. **Financial resources:** Consistent with Phase 1 & 2 of the programme, we have split the regional funding for phase 3 into two elements: regional programme resource funding and regional delivery funding.
   i. Regional programme resource funding – Regional allocations were communicated on 30 June.
   ii. Regional delivery funding - We expect to share initial indicative delivery costs shortly with regional finance teams. The costs will be dependent on the final delivery model (e.g. coadministration, childhood immunisation, etc.) and we will be refining these as the programme assumptions mature.

8. **Children's COVID-19 vaccination:** MHRA have approved the Pfizer vaccine for use in those aged 12+, and the JCVI is examining the evidence. The JCVI will advise the Government on next steps in due course.

Next steps

Systems should **work with local providers, local authorities and regional teams to review their current Autumn/Winter plans**, to ensure alignment with the content of this letter. We will make additional information available as soon as it becomes available to us.

Thank you for your continued efforts in delivering the COVID-19 vaccination programme. We are grateful to everyone in the programme for their dedication in making the COVID-19 vaccination rollout a success.

Emily Lawson
SRO Vaccine Deployment
Chief Commercial Officer

Dr Nikki Kanani
Medical Director for
Primary Care

Professor Keith Willett
NHS Strategic Incident
Director

Please see the link below for the full JCVI interim statement on COVID booster vaccines: https://www.gov.uk/government/news/jcvi-issues-interim-advice-on-covid-19-booster-vaccination

Also see this link: https://www.gov.uk/government/publications/jcvi-interim-advice-on-a-potential-coronavirus-covid-19-booster-vaccine-programme-for-winter-2021-to-2022/jcvi-interim-advice-potential-covid-19-booster-vaccine-programme-winter-2021-to-2022

COVID-19 Vaccine Dosing Intervals – Green Book Update

Please read the changes at the link below:

COVID-19: the green book, chapter 14a - GOV.UK (www.gov.uk)

The Green Book guidelines for Covid-19 vaccine dosing intervals have been updated (1 July) by Public Health England, in line with JCVI guidance.

The guidance states:

"For both adenovirus vector and mRNA vaccines, there is evidence of better immune response and/or protection where longer intervals between doses are used.
Currently, JCVI is recommending an interval of 8 to 12 weeks between doses of all the available COVID-19 vaccines. Operationally, this consistent interval should be used for all two dose vaccines to avoid confusion and simplify booking, and will help to ensure a good balance between achieving rapid and long-lasting protection.
The main exception to the eight week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the minimal intervals outlined below may be followed to ensure that the vaccine is given whilst their immune system is better able to respond."

Action required in response

Given the increase in cases of the Delta variant, giving people the best possible protection from Covid-19 is vital.

Therefore, second dose vaccinations should not be offered earlier than 8 weeks, except in line with the guidance issued by JCVI and the Green Book (for example, transplant patients or those about to undergo immunosuppression treatment where vaccination prior to this would be beneficial).

Any decision to vaccinate earlier than 8 weeks should be made by the patient's responsible clinician or vaccination site clinical lead on a case-by-case basis and must be based on clinical risks and benefits of giving the second dose earlier than 8 weeks. There must be no blanket approach taken by vaccination sites to offer second doses sooner than advised.

Access to vaccine for people with no NHS number - FAQs

Patients, including NHS staff, do not require an NHS number or GP registration to receive a vaccination and should never be denied one on this basis.

Colleagues are encouraged to review the FAQ document addressing access to vaccine with no NHS number, available on FuturesNHS. Colleagues are reminded of the following key points:

You do not need to be registered with a GP to receive a COVID-19 vaccination, and you do not need an NHS number to receive a COVID-19 vaccination.

You do not need to provide ID to receive a COVID-19 vaccination, although (except for Janssen single dose) you will need to provide sufficient information to be contacted for your second dose. This does not mean a person has to give their full or legal name or address.

No one should be turned away from any site or prevented from booking for these reasons; every site and every person should be confident to seamlessly deliver a vaccine to any non-contraindicated adult

User experience feedback has shown that **on the ground**, **individuals are still being turned away from vaccination sites and GP surgeries for these reasons**, and that outreach work to likely groups of unregistered individuals is delayed by these concerns.

Technical information on recording a vaccination in a person without an NHS number is available here with a full step-by-step guide: Outcomes4Health Covid Template update - extended functionality 15.04.21 - COVID Vaccination - IT systems training - FutureNHS Collaboration Platform. We know that one of the main reasons people are turned away is because someone does not know how to record the event.

MHRA - COVID-19 Vaccine Moderna and Pfizer/BioNTech COVID-19 vaccine: myocarditis and pericarditis – revisions to the product information

The Medicines and Healthcare products Regulatory Agency (MHRA) and the Government's independent expert advisory body, the Commission on Human Medicines (CHM), has conducted a thorough review of suspected adverse reaction reports of myocarditis and pericarditis following COVID-19 vaccination.

The CHM has carefully considered the available data and has advised that healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath or symptoms of arrhythmia.

This notification informs you of revisions to the product information for COVID-19 Vaccine Moderna and Pfizer/BioNTech COVID-19 vaccine.

The information for healthcare professionals now reads as follows:

Section 4.4: Special warnings and precautions for use

Myocarditis and pericarditis

There have been very rare reports of myocarditis and pericarditis occurring after vaccination with COVID-19 mRNA Vaccine BNT162b2, often in younger men and shortly after the second dose of the vaccine. These are typically mild cases and individuals tend to recover within a short time following standard treatment and rest.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinated individuals should also seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias.

Section 4.8: Undesirable effects

Cardiac disorders:

Myocarditis, pericarditis (frequency unknown)

The information for UK vaccine recipients has also been updated in line with these revisions.

Government Guidance for People Worried About Astrazeneca 2nd Dose

Colleagues are alerted to the availability of a leaflet for people eligible for COVID-19 vaccination who have had their first dose of AstraZeneca vaccine and have concerns about having the second dose. It is available here.

Vaccination Cards

We would like to remind every vaccination site that a Vaccination Card must be completed every time someone is vaccinated. The card provides an immediate record of the event for the patient and, because it includes details of the time and date of vaccination and the vaccine batch number, is an important safety net if the electronic record is incomplete.

Although the NHS App generates a permanent vaccination certificate, the card remains an important temporary record. Please ensure that it continues to be provided and that those vaccinated are reminded to keep it safe and present it when they present for a subsequent dose.

Operationalising JCVI guidance for those under 40

On the 7th May, JCVI updated its guidance on the choice of COVID-19 Vaccine available for those under the age of 40. This states:

JCVI advises that, in addition to those aged under 30, unvaccinated adults aged 30 to 39 years who are not in a clinical priority group at higher risk of severe COVID-19 disease, should be preferentially offered an alternative to the AstraZeneca COVID-19 vaccine, where possible and only where no substantial delay or barrier in access to vaccination would arise.

Colleagues are therefore reminded of the below:

- All those under the age of 40 who are yet to have their first dose should be preferentially offered the Pfizer BioNTech or Moderna vaccines, unless there is a clinical reason that precludes the use of either of these alternative vaccines. e.g. PEG allergy.

- If there is a clinical reason for a person under 40 to receive vaccination with AstraZeneca, informed consent following a discussion about risks and benefits to the individual must be obtained. In these circumstances, authorisation to proceed must be obtained from the Senior Clinical Lead on duty before the person receives their vaccine.

This is particularly important for those sites running drop in or pop up sessions. This may mean that the person is advised to attend a different vaccination site or return on a day when alternative vaccines are available.

Further information to support sites with this is available in the appendix.

Appendix I

Further Information on vaccinating those under the age of 40.

Current forecasts indicate that it is possible to complete phase 2 by offering the Pfizer-BioNTech or Moderna vaccines for all individuals under 40 years of age who are yet to receive their first dose, without impacting on timelines for delivery.

There are currently no safety concerns following receipt of the second dose of the AZ vaccine. Therefore, all those who have received a first dose of the AstraZeneca vaccine should continue to be offered a second dose of the AstraZeneca vaccine, irrespective of age, except for the very small number of people who experienced blood clots with low platelet counts from their first vaccination. See the section on 'Exceptional circumstances in which a different second vaccine to the first can be given' in the PHE Information for Healthcare Practitioners).

Interchangeability of Vaccines

There is currently no evidence on the interchangeability of the COVID-19 vaccines therefore every effort should be made to ensure that the same vaccine as the first dose is given. Preliminary data from a study of 463 people in evaluating the interchangeability of COVID-19 vaccines suggests that a mixed schedule appears to lead to more systemic side effects after the second dose, such as fever and muscle aches. More individuals who received the AZ vaccine for the first dose and Pfizer for the second dose reported fever compared to those who received the AZ vaccine for both doses.

Informed Consent

Please see updated chapter 2 of the green book for further information regarding consent.

For AstraZeneca Vaccine the informed consent discussion should also include the following information:

- clear information on the extremely rare thrombosis/thrombocytopenia adverse events

- how to monitor for symptoms that might be related to the adverse event
- what action should be taken by individuals and health professionals in the event of such symptoms arising.

Further information to support these discussions is available here: Information for healthcare professionals on blood clotting following COVID-19 vaccination - GOV.UK (www.gov.uk)

Modern Slavery and Human Trafficking

It is important that all staff are made aware of and review the current policies and initiatives that support the Government's objectives to eradicate modern slavery and human trafficking. It is also important that all staff are aware of the significant role the NHS plays in both combatting it and supporting victims.

The NHSE modern slavery and human trafficking statement is available here while further information and supportive materials are available from the Modern Slavery and Exploitation Helpline here.

Modern slavery is a hidden crime, and its victims may be especially isolated during the coronavirus outbreak. It is not the health professional's job to decide if someone is a victim, but if you do have concerns, raise them with your safeguarding lead or contact one of the organisations listed in the attached.

Training Guidance For COVID-19 Vaccinators - Summary and Top Tips

A summary of published training guidance from Public Health England (PHE) and the national programme, as well as reminders and top tips for streamlining local training, can be found here on FutureNHS.

Accessing Lateral Flow Tests NHS Asymptomatic Staff Testing: Changes to How Staff Access Lateral Flow Tests

The way that NHS staff access lateral flow device tests is changing. From week commencing 5 July, staff will be able to order their tests directly through the Government ordering portal. A letter setting out the changes to the NHS staff testing programme has been issued to system leaders.

Overseas Vaccinations: Reminder

Colleagues are advised to review the update to the COVID-19 vaccination programme guidance for healthcare workers which includes vaccine interchangeability guidance where someone may have had a vaccine overseas in Appendix 1. Please review guidance by clicking on the link.

All COVID-19 vaccination queries and incidents should be directed to: england.swcovid19-cars@nhs.net