



ICARS Newsletter

Issue 61: 29th October 2021

Immunisation Clinical Advice Response Service

About this bulletin:

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

PLEASE SHARE WITH ALL RELEVANT STAFF INVOLVED WITH THE
VACCINATION PROGRAMME

Please note that ICARS operates from 9am - 5pm Monday to Friday.

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1. Out of School Offer for Vaccination of 12-15 Year Olds

A. Next Steps

The [system letter published](#) on October 19, outlined the next steps for vaccinating the 12-15 year old group. The introduction of multiple places where young people can access vaccination heightens the need for providers to use electronic Point of Care systems live. This supports safety by reducing the chance of duplicate vaccination by timely and accurate event recording and wasted appointments.

The recently published [Top Tips for Improving Data Quality](#) emphasises the importance of undertaking data entry live. If providers find themselves in situations where they cannot use the systems live, then it is important that information is uploaded onto digital platforms as quickly as possible. The [Safety Huddle checklist](#) suggests this needs to be undertaken on the same day. Consequently, it is important that vaccinators emphasise the question in the Point of Care systems which asks if any vaccination has been received within the preceding 7 days.

B. For information and action only if contacted by NHS Regional Teams

On 19 October, we wrote to ICS and STP leaders, copied to all LVS sites, about out-of-school vaccination of children aged 12-15 years – see the [letter here](#). Vaccination Centres and Hospital Hubs are preparing to provide this service and appointments will be made available on the National Booking Service and 119.

LVS sites may be contacted by their regional team to consider vaccination provision for children and young people aged 12-15 years where there is a need

for additional capacity and where this will not affect efforts across the system to support wider access to primary medical services. More detailed information will be shared with sites that the regional team consider could be commissioned to vaccinate this cohort.

If a Community Pharmacy site is being considered, then regional teams will follow the commissioning process set out in the Ops Note and attachments circulated to all CP site leads by their RVOC / SVOC on 19 or 20 October.

LVS sites must not start making a universal offer of vaccinations to all children and young people aged 12-15 years unless commissioned to do so

C. 12-15s programme vaccine supply ordering for out of school providers

All Local Vaccination Services, Vaccination Centres and Hospital Hub plus sites providing vaccinations to 12-15s year olds, will need to use the Supply Planner/Ordering Platform to request vaccine for all future deliveries from the week commencing 1 November.

For deliveries in the w/c 1 November all sites will need to have made their vaccine volume requests within the Supply Planner against their maximum caps by Tuesday 26 October.

All vaccine allocations for the out of school 12-15s programme for the week commencing 25 October have already been completed manually, with deliveries to LVS sites taking place on their standard fixed delivery. VC and HH+ sites were able to begin receiving deliveries from Saturday 23 October.

2. Updated 27th October: Vaccination for Clinical Trial Participants V0.2

Please find attached a guidance note which provides additional guidance following on from the cascade of 12/10/21 on the delivery of vaccination for those who have been participants in vaccine trials across England. The guidance contains information from the National Institute for Health Research (NIHR) and links to further information. In addition, it describes the partnership process required between the Principal Investigators from trial sites and the site leads of the matched Hospital Hub/HH+.

Guidance was sent to Hospital Hubs/HH+ offering vaccination to Novavax trialists on 20 October. The guidance is now to be cascaded to Hospital Hubs/HH+ who will be offering vaccines to trialists participating in ComCOV/ ComCOV2 and Valneva trials.

3. Reminder: Accessing workforce to support phase three delivery of the booster programme

As primary care continues to deliver phase 3 of the vaccination programme, we want to ensure Local Vaccination Services know how they can access additional workforce where required.

This includes:

- Being clear how the national workforce offer can support you and your service.
- How you access and draw down from national workforce supply routes.
- Understand the flexibilities offered by the national protocol and how this can help you with a sustainable workforce model. Please contact your [Lead Employer](#) who are the workforce hub for your local area and they will support you as much as possible to access additional workforce. There is also currently no charge for the cost of additional staff deployed from lead employers now extended until the end of January 2021. The national protocol is the preferred legal mechanism for delivery as it allows the tasks of the vaccination process to be broken down into component parts, which means a more diverse workforce can be utilised in the delivery model. This includes unregistered workforce who can dilute, draw up and administer the vaccinations releasing registered health care professionals to support core primary care services. Please refer to the [LVS National Workforce Support Offer Toolkit](#) as a practical guide including suggested workforce models. In addition, there is a simple [onboarding guide](#) for Community Pharmacies. Email the national workforce team PCNCP.workforceescalation@nhs.net if you need any support.

4. St John Ambulance workforce support for phase three of the vaccination programme

St John Ambulance (SJA) continue to be a key part of our workforce offer into phase three of the vaccination programme. In addition to the vaccination volunteer role that SJA have provided to date in the programme, there is the ability to access three additional offers of support from SJA to support the vaccination of adults in phase three.

- SJA volunteers are trained and competent to be able to administer flu and COVID-19 vaccinations, if you are wanting volunteers who are trained in flu this information will need to be added to your SJA request.
- SJA can provide support to PCNs to deliver boosters to care homes. They can provide trained volunteers to vaccinate and provide post-vaccination observation support. The PCN will need to provide the clinical and administrative workforce. You can find more details here on the [offer and workforce model](#). Support can be requested by completing this [form](#) ensuring at

least five days' notice is provided. If you have any queries, please contact SJA at NHS-Vaccinations@sja.org.uk

- SJA are able to provide Mobile Treatment centres which are vehicles which can be used to provide static pop-up vaccination sites. This offer can be used to support hard to reach geographies and communities to improve cohort uptake. You can find more details [here](#). SJA need a minimum of 10 days' notice to support deployment of mobile treatment centres. The full details of what support can be provided by SJA can be found in the adult workforce considerations for phase three, which is available [here](#).

5. Co-administration design principles

The [workforce and training toolkit](#) has now been updated to include some design principles, clinical red lines and training standards that need to be considered when planning to co-administer flu and COVID-19 vaccines.

6. UKHSA COVID-19 vaccination programme publications

Presentations from UKHSA on recent COVID-19 vaccination programme publications are now available on the Vaccine Equalities Futures workspace. They include links to updated information and downloadable resources for children and young people as well as boosters, and third doses.

[UKHSA COVID-19 vaccination programme publications on Children and Young people](#).

[UKHSA COVID-19 vaccination programme booster and third dose publications/translations](#)

7. Encouraging pregnant women to get COVID-19 vaccine

We continue to encourage pregnant women to get the COVID-19 vaccine as [new data](#) shows that nearly 20 per cent of the most critically ill COVID patients are pregnant women who have not been vaccinated.

COVID vaccination in pregnancy is considered safe and is recommended by the Royal College of Obstetricians, Royal College of Midwives and the UK Tetralogy Service. The Royal College of Obstetricians and Gynaecologists and the Royal College of Midwives have both recommended vaccination as one of the best defences for pregnant women against severe COVID-19 infection, while the independent JCVI confirms the jab has been shown to be effective and safe for women carrying a baby.

Resources to support clinicians' conversations with pregnant women are available here:

[Pregnant? Have your Covid-19 vaccines posters - Health Publications](#)

[NHS England and NHS Improvement North West » Covid-19 Vaccination – Maternity Vaccine facts - RCM](#)

[Covid-19 vaccines, pregnancy and breastfeeding \(rcog.org.uk\)](#)

8. Case Studies

The COVID 19 Vaccination Programme [Improvement Hub](#) has published a number of [case studies](#) to share learning and improvement work across the programme.

A [case study](#) is available sharing [learning](#) regarding infection control at a Vaccination Centre. Do have a read and share the improvement nuggets with your teams.

[Learning re infection control at a Vaccination Centre](#)

9. Operational Note to all sites: Preparation for the Self-declaration pathway of Immunosuppressed patients for COVID-19 vaccination and reminder to vaccinate patients presenting via a referral letter

- [JCVI recommends](#) that people aged over 12 years with a severely weakened immune system should be offered a third dose as part of their primary COVID-19 vaccination course. Please note that this operational guidance is aimed at patients aged 16 years and above. The guidance for 12 to 15 year olds continues as is current practice, and is outlined in our operational [ops note from 4 October](#). In line with this guidance, sites that are compliant with the readiness requirements to vaccinate 12-15-year olds shall continue to vaccinate patients aged 12-15 year old who present with a referral letter.
- Further guidance was published by NHSE/I on identifying and inviting Immunosuppressed individuals for a 3rd dose with information provided in [our letter from 30 September](#) to NHS trusts and [our letter to Primary Care Networks](#), to support access and increase uptake for this important group.
- [We have asked hospital consultants](#) to verify all patients identified as eligible for a third primary dose within their care, contact these patients to discuss the optimal timing for administering a third dose and either arrange for a vaccination directly, or send a letter to the patient, copied to their GP, to support vaccination elsewhere. If a patient presents at your site with one of these letters, then please administer their vaccination.

- This note provides operational guidance on the actions and preparations required by all vaccination sites to administer the third primary COVID-19 vaccination dose to immunosuppressed patients. These are the most vulnerable patient group and we need to ensure maximum accessibility for safe and prompt vaccination
- As outlined in our [ops note from 4 October](#), for patients attending with a referral or recommendation from their GP or clinical consultant, vaccination can proceed either under the Patient Group Directive (PGD) or National Protocol. Please make all staff, including front of house volunteers, aware of the third primary dose vaccination for immunosuppressed patients that patients presenting with a referral or recommendation are not turned away.
- Shortly, **individuals will be able to self-declare eligibility for a 3rd dose vaccination**. Site leads together with their regions and systems must prepare for a self-referral pathway that will be open to eligible immunosuppressed patients. These individuals will be able to seek vaccination at all vaccination sites which offer walk-in services.
- We have issued clinical guidelines [attached] to support this pathway. Further operational guidance and information on this self-referral pathway will be made available shortly. Sites will be required to have a prescriber available who can be on or off-site. An overview of the required local process is outlined below.

FOR IMMEDIATE ACTION

With immediate effect, site leads are required to rapidly develop and implement the following processes and prepare for the self-referral pathway.

- Site leads must ensure that clinical staff with prescribing rights are available, which may be remotely, for advice and to provide authorisation to vaccinate under the PGD/Protocol as outlined below. For sites that do not have access to a prescriber (on site/off-site) available at present, they should work with regions to identify solutions such as 'on-call' arrangements with a prescriber that could be shared across sites at a system level or in addition to other roles to ensure that this role can be more easily filled.
- [COVID-19 infection prevention and control \(IPC\)](#) must be adhered to at all times. It indicates the measures required if a pathway is considered high or medium risk.- Regional leads should work with sites to ensure the following processes are in place, and that appropriate clinical expertise is accessible at all times to support clinical assessment.
- In the case that a patient attends without a GP or consultant referral and self-declares eligibility, sites with access to a prescriber who can review the patient should vaccinate the patient under the PGD or National Protocol or direct administration under a PSD by the prescriber, following the process outlined below. The clinical assessment must be followed by a discussion with a prescriber to support vaccination under a PGD or the National Protocol.

- Where a patient presents via the self-referral route and the site does not have a prescriber available, the clinical site lead should have a conversation with the patient and advise the patient that currently the self-referral pathway is not available at Vaccination Centres and Community Pharmacies but will be made available shortly. The patient can contact their GP/ consultant to obtain a referral letter so that the vaccination can take place via the PGD or National Protocol.

A. Welcoming patients attending for their 3rd primary course dose at a vaccination site

- Sites must put in place processes to ensure all teams, including front of house volunteers, are briefed on the 3rd primary dose vaccination for eligible patients.
- Patients will identify via bringing one of the forms of proof outlined in the following section 2, either with a referral or via a self-declaration process. Sites must not turn these patients away for having not reached the 6-month eligibility criteria for a Booster vaccination. This is a third dose as part of the primary course rather than a Booster vaccination. Please make staff aware that some patients may incorrectly refer to this third dose as 'booster' vaccination.

B. Confirmation of eligibility at arrival:

Patients may identify via a number of ways:

For the referred pathway:

1. a **letter of referral or recommendation** from the patient's GP or consultant

For the self-referral pathway via the following:

2. a copy of relevant hospital letters confirming either diagnosis or medication relevant to diagnosis. These will need clinical interpretation.
3. proof of medication e.g. repeat prescription or medication box for immunosuppressive medication (where this is relevant)

The above information is needed to support the prescriber authorisation step.

Where an individual **self-refers and attends with the evidence above**, then a clinical assessment will be required. Sites must put in place processes to direct self-declaring patients in a timely way to the clinical lead on site. Sites need to make preparations, and work together with their regional team and systems to find a local solutions to access a prescriber who may be on or off-site.

C. Clinical assessment and administering vaccines: referral route

Where a patient attends following **a referral or a recommendation** from their consultant or GP to receive their third dose, vaccination should proceed either under the Patient Group Directive (PGD) or National Protocol.

D. Clinical assessment and administering vaccines: self-referral route

The administration of vaccines is undertaken using the PSD, PGD or national protocol legal prescribing tools. It is important to ensure that vaccination of individuals takes place in accordance with these tools.

To support vaccination where a patient is self-referring the following elements of a patient pathway will need to be in place.

- A clinical assessment step where it will be confirmed if an individual meets the criteria for a vaccination using the green book information <https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a> and through obtaining some clinical information such as medication being taken.
- Access to a prescriber to provide authorization for a vaccination to take place under a PGD or protocol if the clinical lead on site is not a prescriber. Sites will need to identify how access to a prescriber can be put in place during vaccination sessions. The prescriber role can be remote with an individual potentially overseeing a number of sites according to local need. (Note that a prescriber can be a medical prescriber or independent nurse or pharmacist prescriber). Where an assessment is made that an individual cannot have a vaccination there will need to be a locally based escalation process where further action is taken where appropriate to support an ability for vaccination to take place at a future date. Further guidance will be provided shortly to support design of an escalation process for those sites that do not have a prescriber on site or remotely.

E. Administering and recording Vaccines

For patients presenting for a 3rd dose vaccination, JCVI recommendations are that a mRNA vaccine is preferred. This would be a full dose or 0.3mls of Comirnaty (Pfizer-BioNTech) or a full dose 0.5 mls of Spikevax (Moderna). For those aged 12 to 17 years, the Comirnaty (Pfizer-BioNTech) vaccine is preferred. **It is important to note that the dose of Spikevax (Moderna) for patients with immunosuppression for their third dose of the primary course, is different from that to be administered for other individuals receiving boosters.** The dose of Spikevax (Moderna) for boosters is 0.25mls.

- The 3rd dose should be recorded in the Point of Care system as a booster. For patients that are self-referring, sites should briefly record the rationale in the PoC system.

F. Post-vaccination observation

Sites must ensure sufficient space is available for required post-vaccination observation for this group in line with existing requirements.

10. UKHSA update following FSN in relation to El Dawlia ico Med - Sterile Hypodermic Syringe. 2ml syringe with 21G x 1.5” Safety Needle

PLEASE NOTE THAT THIS MESSAGE SUPERCEDES RVOC5872 SENT 23/10/2021 AT 17:32

UKHSA has been made aware of a potential issue with specific production lots of the El Dawlia ico Med - Sterile Hypodermic Syringe with Combined Safety Needle manufactured by International Medical Supplies (IMS) Euro Ltd. Specifically lot numbers 2105 and 2106.

There have been no reports of patient harm but IMS has issued a Field Safety Notice (FSN) to voluntarily recall these products. You may have already received the FSN and an accompanying note from UKHSA. This communication supersedes the note issued by UKHSA.

DHSC, UKHSA, MHRA and NHS England and NHS Improvement have reviewed the FSN issued and conducted a thorough risk assessment. The FSN relates to:

- A small amount of additional lubricant in the barrel and/or luer tip of the syringe. This may make the lubricant visible in the luer tip. The fluid is entirely safe and a normal constituent and does not affect the delivery of the vaccine. However, where it is visible, the entire unit should not be used and another opened.
- Occasionally, syringes and/or needle may be upside down within the package meaning users may inadvertently hold the wrong end of the product and therefore increase risks of not maintaining aseptic technique. As this could be the case with these syringes or needles, please take extra care when opening the packaging to maintain aseptic technique. Where alternative suitable products are available please use these until all product replacement is complete. If it is not possible to use an alternative, vaccinations using the products identified should continue. From a clinical perspective, the assessment undertaken by UKHSA indicates that the risk of delaying vaccinations for patients far outweighs the issues identified by the FSN, along with the steps outlined above. UKHSA will be continuing to replace the impacted products and will be issuing a priority push of alternative products to sites that have received batches of the products identified by the FSN early next week.