

ICARS Newsletter

Issue 62: 5th November 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 SHAREWITH ALL RELEVANT STAFF INVOLVED WITH THE VACCINATION PROGRAMME

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

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1. UPDATED: AstraZeneca PGD

The Patient Group Direction for COVID-19 Vaccine AstraZeneca (ChAdOx1-S [recombinant]) has been updated and is available here.

The National Protocol has also been updated now on UKSHA's website here: https://www.gov.uk/government/publications/national-protocol-for-covid-19-vaccine-astrazeneca-chadox1-s-recombinant

2. Moderna (SpikeVax®) COVID-19 vaccine

Following an increase in the numbers of queries relating to Moderna Vaccine from sites we have summarised some key information on use of Moderna below. Clinical teams should familiarise themselves with the information in the green_book, the JCVI recommendations on the use of Moderna mRNA (SpikeVax®) vaccine as well as the summary of product characteristics.

Summary of Clinical evidence:

Moderna (Spikevax®) COVID-19 vaccine offers a high level of protection against COVID-19; the main large trial showed that the vaccine has a 94.1% efficacy in adults. Another study showed that an additional dose of Spikevax increased the ability to produce antibodies against SARS-CoV-2 in organ transplant patients with severely weakened immune systems. Data showing that a booster dose of Moderna given 6 to 8 months after a second dose led to a rise in antibody levels in adults whose antibody levels were waning. The booster dose consists of half the dose used for the primary vaccination schedule (the primary vaccination schedule includes first, second and third primary doses where eligible).

Boosters:

To note that for boosters both Pfizer and Moderna covid-19 vaccines should be given. Both are mRNA vaccines and work in a similar way. Pfizer Vaccine is the recommended vaccine for children and therefore supplies need to be prioritised for this patient cohort. JCVI has reviewed data from the various booster clinical trials that indicated that **mRNA vaccines** provide a good booster response. Guidance from JCVI states: 'Individuals may be offered a half dose (50µg) of the Moderna (mRNA-1273/Spikevax®) vaccine, which should be well tolerated and is also likely to provide a **strong booster response**.'

Further to the above the European Medicines Agency have now licensed the use of Moderna as a half dose booster, further information on this is available here.

3. Griffith's and Nielsen combined needle and syringe products for dilution of Comirnaty (Pfizer BioNTech) vaccine

Since 21st October UKHSA has been issuing a new combined needle and syringe for the dilution of the COVID19 Pfizer vaccine.

The new dilution product is the Vanishpoint Safety Hypodermic Needle & Syringe 21G Green x 38mm (1.5 inch) with 3ml Concentric Syringe supplied by Griffiths & Nielsen (G&N). This product includes a safety needle feature (retractable needle).

The technique for using this product for dilution differs to previous products due to the retractable needle mechanism. This affects vial equalisation and removal of air bubbles. G&N have developed training advice, including videos, to address this.

The training advice can be found here.

4. IMS Field Safety notice letter - specific production lots of the El Dawlia ico Med - Sterile Hypodermic Syringe with Combined Safety Needle manufactured by International Medical Supplies (IMS) Euro Ltd.

We have been made aware of a potential issue with specific production lots of the EI 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.

5. Booster COVID-19 Programme Updates and Reminders

A. Who is Eligible for a Third Dose of COVID-19 Vaccine?

We know there are some on-going queries about who is eligible for a third dose of COVID-19 Vaccine. People who are severely immunosuppressed due to underlying health conditions or medical treatment are being identified and offered a third primary dose of COVID-19 vaccination to help reduce the risk of getting seriously ill. JCVI guidance recommends that a third dose be offered to individuals aged 12 years and over with severe immunosuppression, including those who are being treated for conditions such as cancer or for those with long-term chronic conditions where their immunity is significantly affected by regular medication.

A list of conditions and treatments which identifies people who are considered severely immunosuppressed has been published by the JCVI.

We have produce a <u>script</u> and <u>poster</u> to help healthcare professionals identify this group.

B. Operational guidance: preparations to enable NBS advance booking of booster vaccinations

Planning is underway so that people in eligible cohorts will soon be able to book an appointment through the national booking service 30 days in advance of the date from which they can get the booster, which is 182 days after the date of their second vaccine.

This means that from 152 days after the date of their second vaccine appointment, eligible people can book their advance appointment for a booster. The actual appointment dates will still only be from 182 days after the date of their second vaccine.

The timing of invitations will also be changed so that people receive them in advance of their 182 day eligibility date (exact timing TBC).

A communications strategy is in development so this is effectively and consistently communicated to the public. For now, please therefore limit any communication about this to what is needed to support this operationally.

To enable this advanced booking route all vaccination teams using the NBS are required to action the tasks outlined in our ops note from 28-10-2021 and as per <u>guidance</u> provided to sites and regional teams.

C. Administration of a booster dose less than six months after the second dose

Booster vaccines are being scheduled at a six month interval (182 days) from the second primary dose. As advised by the JCVI, this interval will automatically help to prioritise older and more vulnerable patients.

The Green Book has been updated (<u>COVID-19 Greenbook chapter 14a</u> (<u>publishing.service.gov.uk</u>) to clarify that for operational reasons administration of Booster doses may be brought forward to a minimum of five months in certain circumstances including:

- attending a care home setting to enable all residents to be vaccinated in the same session
- visiting housebound patients in which it will be beneficial to the eligible individual to receive the vaccine at the same time as other intervention/treatment (for example influenza vaccine)
- where an otherwise eligible individual attends for another intervention (for example influenza vaccine) or who presents for another reason at a vaccination clinic (for example those who present opportunistically and are nearing six months)

For those about to receive immunosuppressive treatment the booster may be brought forward to a minimum of four months (~120 days) to avoid giving the booster when the immune system is less able to respond. Such individuals will need to be scheduled for additional boosting at a later date, currently expected to be around six months after the last dose.

Third doses given to those who were severely immunosuppressed at/around the time of their first or second primary dose do not count as booster doses. These individuals are expected to also require a booster after another six months, but JCVI will review evidence from trials of boosting in this population and issue further advice on the optimal timing for this group.

ACTION NOW REQUIRED

All vaccination sites are now requested to ensure that they have read this update and have taken the following actions:

- Updated all relevant vaccination site procedures and briefed all members of the vaccination team of the operational reasons to administer Booster vaccinations less than six months after the second dose.
- Noted that the Point of Care system will alert users to the existing 182-day guidance however, it will not stop a user from recording a vaccination event before this time.

Please Note that the changes outlined in the green book will currently need to be administered using a Patient Specific Direction

D. Please continue to identify and contact immunosuppressed people for their third primary dose

As you know, some people are eligible for a third primary course dose because they are immunosuppressed, either because of an underlying health condition such as cancer or a long-term chronic condition where their immunity is affected by medication. This third primary course dose is different to a booster dose, which is currently recommended by the JCVI for over-50s, clinically vulnerable patients and frontline health and social care workers, to take place from six months after the primary course of two or three doses.

We recently sent direct letters and text messages to people who may need this third dose so they can discuss it with their GP or hospital consultant; and we know your teams have been working hard to identify and contact these people – thank you for prioritising this and your continued work in making sure these people are contacted and vaccinated is critical. Can you please remind your front desk team of the difference in legibility for the immunosuppressed group from the booster.

E. Guidance on administering and recording third primary doses for severely immunosuppressed individuals

How do I record a third primary dose in my Point of Care System? (for all delivery models)

From 14 September, functionality was introduced to record third doses as a "Booster" in your Point of Care system. Please do not use the first or second dose fields to record these vaccines as the individual receiving the third dose should have already received a first and second dose. If a Booster vaccination is recommended for this cohort by the JCVI, these will also be recorded as a 'Booster'. We will provide further advice on this in due course, including how you will be able to record a booster for severely immunosuppressed individuals if recommended.

6. 12-15 Year olds COVID-19 Programme Updates and Reminders

A. South West School Aged Contact details

For your convenience, we are sharing the contact details for your local School Aged Immunisation teams in the South West who are the primary vaccinating service for 12-15 year olds in schools.

Region	Provider	Address		Contact email / website
Bristol, North Somerset & South Gloucestershire	Sirona Care and Health CIC	Kingswood Locality Hub, Alma Road,	764	Email: <u>sirona.sch-</u> <u>imms@nhs.net</u> Website: <u>https://www.sir</u> <u>ona-</u> cic.org.uk/nhsservices/s
		Kingswood BS15 4DA 3 Station Road, Pill, BS20 0BA	01275 373 104	ervices/school-age-flu- vaccination/
Bath & North East Somerset, Swindon & Wiltshire	Virgin Care Ltd	Wiltshire Children's Community Services, 1st Floor Technology House, Unit 10 High Post Business Park, SP4 6AT	0300 247 0082	Email: Vcl.immunisation s@nhs.net Website: https://wiltshire childrensservices.co.uk/ immunisation-service/
Cornwall	Kernow Health CIC	1st Floor Cudmore House Oak Lane Truro TR1 3LP	01872 221105	Email: kernowhealth.schoolim munisations@nhs.net Website: https://www.ke rnowhealthcic.org.uk/pri mary-care- services/school- immunisations/
Devon	Virgin Care Ltd – Devon	Immunisation Team, Agricultural House, Pynes Hill, Rydon Lane, Exeter EX2 5ST	0300 247 0082	Email: Vcl.immunisation s@nhs.net _ Website: https://wiltshirechildrens services.co.uk/immunis ation-service/

Dorset	Dorset HealthCare University NHS Foundation Trust	Acorn Building St Leonards Hospital Ringwood Road St Leonards BH24 2DW	01425 891162	Email: dhc.immsenquiries@nh s.net Website: https://www.dorsethealt hcare.nhs.uk/schoolagei mms
Gloucestershire	NHS Foundation	•	0300 421 8140	Email: GHC.Immunisation@gh c.nhs.uk Website: https://www.gh c.nhs.uk/our-teams- and- services/immunisation/
Somerset	Aged Immunisation Nursing Team	Bristol Road, Bridgewater,	0300 323	Email: somersetsaint@s omersetft.nhs.uk Website: https://www.so mersetft.nhs.uk/saints- school-age- immunisation-team/

B. Grab A Jab Walk-Ins for COVID-19 Vaccination Offer for 12-15-year-olds

Following the launch of the "Out of School" COVID-19 vaccination offer for 12-15-year-olds through the National Booking System, the Grab a Jab website has been updated to enable the age ranges "12-15" and "12 and over". Walk-in sites that have been sent to the national team as part of the regional returns nominating sites to vaccinate 12-15's should now upload availability for this service onto 'grab a jab' website. Please ensure visibility on the website for dates from Saturday 30th October onwards. There will be a range of communication activity planned to support this offer.

C. Record of Authorising Clinician on Pinnacle for vaccinations for 12-15vear-olds

As described within the National Protocol, all sites administering Covid-19 vaccines via this mechanism are required to have a Clinical Supervisor who is present, and responsible for the overall provision of clinical care provided under the legal authority of the protocol. The Clinical Supervisor must be a registered doctor, nurse or pharmacist who is competent in all aspects of the protocol. Therefore, it should be noted that the Authorising Clinician in this context within Pinnacle corresponds to the Clinical Supervisor described above. Additionally, records of vaccination events can only be submitted if this field is by appropriately with the relevant details.

In many cases, the Authorising Clinician (Clinical Supervisor) may not be the healthcare professional performing the consent process or clinical assessment

for the patient who is to be vaccinated. However, these specific tasks must still be carried out by a registered healthcare professional. In this scenario please capture the responsible clinician in the "Authorising Clinician" field within Pinnacle. This needs to be a registered doctor, nurse or pharmacist but will be expanded in the coming weeks so that those with a HCPC, GDC or GOC registration can be entered.

D. REMINDER Vaccination Operational Support Teams (VOST) are available to support vaccinations (COVID-19 and Flu) and 12-17-year olds

VOST teams are trained and ready to support COVID-19 and flu vaccinations, including 12-17-year olds and can often be deployed at pace. They are made up of an equal number of Registered Healthcare Professionals and Unregistered Vaccinators.

The process for requesting these teams has been reviewed and alongside the current process of requesting via your Lead Employer, NHSP will also now be engaging with sites directly to understand potential new requirements. Where new requirements are identified, NHSP will work with the Lead Employer and the site to ensure the appropriate documentation, recruitment and deployment is in place over a c.4-week period. Where teams are already available these can be deployed at pace.

Please contact your <u>lead employer</u> for the latest deployment details and availability within your area.

E. REMINDER Checking a child's age

Please can we remind all staff of the need to carefully check the age when anyone presents for vaccination, particularly when vaccinating children because their appearance can be misleading. For those vaccinating at schools, please check carefully whether children are being invited based on their age or their year group – if the latter, **those under 12 years should not be vaccinated**.

Cominarty (the Pfizer vaccine) is not authorised for children under 12 years in the UK, nor is it recommended at present by the JCVI. If you are vaccinating children, always confirm the child's stated age by asking for their Date of Birth and checking that against the date of the session. Any instance of a child under 12 years being inadvertently vaccinated must be reported to the Site Manager immediately, treated as an adverse incident and, if applicable, managed as a potential safeguarding issue.

There are plenty of checks and balances built into the vaccine programme to avoid under-age vaccination - see last week's "Top Ten Hints" and the "Clinical Safety Checklist" referenced above. The Pinnacle system also has built in warnings to alert staff if a child is under 12 years — another excellent reason to record all vaccination events electronically, in real-time.

F. UPDATE Readiness check-list B for children

A revised checklist B (version 4) is now available on NHS Futures. The revisions are minimal, but adjustments have been made to clarify that the check-list applies to all children aged 12-15 years. The checklist has also been updated to reflect the decision to give a greater choice of access to parents or children within the Clinically Extremely Vulnerable group. The updated checklist B is available here.

G. Tens of thousands of 12 to 15-year-olds booked in for COVID-19 jabs as half-term drive continues

More than 80,000 young people aged 12 to 15 have booked their COVID-19 vaccination since online bookings opened five days ago. Following the introduction of the extra option for getting children vaccinated came online, bookings are now being taken up at a faster pace, with almost 33,000 bookings one day alone – thousands every hour.

Around half a million young people in this age group have already been jabbed as the vaccination rollout, the biggest and fastest in NHS history continues to protect the country against the virus. Thousands of schools have been visited since rolling out the jab to 12 to 15-year-olds at the end of September – just a week after updated guidance from the government. Over one hundred existing vaccination centres are already getting families through their doors with more and more expected to come online this week. Over 2.5 million 'follow up' letters are landing on doorsteps this week inviting parents and children to book a vaccination online through the National Booking Service.

Find more out about the half-term drive success here.

7. Maintaining an accurate clinical record through Point of Care systems

This is a reminder to sites that in order to maintain an accurate clinical record, COVID-19 vaccination event recording in point of care systems should be completed when administering the vaccine. We expect that the majority of COVID-19 vaccination events are recorded contemporaneously with administering the vaccine but where this is not possible, these are entered within 48 hours of the vaccination event as best practice.

In the exceptional case where COVID-19 vaccination events have not been recorded in a point of care system 7 days after the vaccination event took place, sites should not enter the COVID-19 vaccination event in the point of care system and instead, can now access the Vaccine Data Resolution Service (VDRS) to support vaccination record entry and queries

via: scwcsu.recall.vdrsquery@nhs.net.

This service aims to resolve missing or incorrect vaccination records for people vaccinated in England who have a current NHS number and are registered with a General Practice in England. This service should also be used november sites if a person presents for vaccination and has missing vaccination records relating to vaccine administered at sites elsewhere in the England and requires sites to complete a form for the team to process. There will be more information, including the necessary forms, being provided to site leads to access the VDRS service to resolve any outstanding data queries beyond 7 days in the coming weeks.

8. Supporting shared decision making in COVID-19 vaccination

Shared decision making is an approach where healthcare professionals, patients and their carers share available evidence-based information while exploring the patient's values and priorities to achieve informed choices. Further information is available from National Institute of Health and Care Excellence (NICE) here.

Since the start of the COVID-19 vaccination programme, clinical teams have been supporting shared decision-making discussions with citizens who may be hesitant to accept the offer of vaccination. This process makes sure the person understands the risks, benefits and possible consequences of different options through discussion and information sharing. It can be supportive for citizens who may be hesitant to receive a particular vaccine type and may otherwise decline the offer.

Sites should ensure that all citizens who plan to leave the premises without continuing with the vaccination process are offered the opportunity to speak with a clinical member of team in order to support a shared decision-making discussion.

9. Vaccination of those who received COVID-19 vaccine overseas

UKHSA have published information for healthcare practitioners on COVID-19 vaccination received overseas. This document can be used by clinicians to provide clinical advice on whether additional doses would be beneficial to enhance protection for those who received COVID-19 vaccinations overseas.

10. Clinical safety checklist

The Clinical Safety Checklist ("The ABC of Vaccination") has been updated and is available at here. The Checklist provides a simple way to structure a safety huddle before a vaccination session and is designed to be used at any site. The checklist now includes a short summary of all current clinical guidance relating to

the vaccination programme. Please continue to provide any feedback as we will update the checklist on a monthly basis.

11. Managing the vaccines in practice

Sites are reminded to make sure they are aware of and are working to the most up to date versions of all guidance, PGDs, National Protocols and standard operating procedures when planning vaccination clinics; these are updated on a regular basis. Most answers to clinical queries can be found in the Green Book or the UKHSA information for healthcare professionals.

<u>Standard operating procedures</u> on vaccine handling and principles to support sites with management of <u>multiple vaccines</u> are available from the specialist pharmacy service. Guidance on <u>good cold chain management</u> and transporting vaccines is available in the above SOPs and in the <u>Mobile and Roving Standard operating procedure</u>. Ensuring that the right vaccine is given at the right dose to the right citizen is of paramount importance as the complexity of the programme has increased.

Robust front-end triage is required to clearly identify which vaccine(s) each patient is due to receive and to direct them into the correct queues. Is it recommended that a specific colour (tray or queue distinguisher sticker/card) is assigned to a specific vaccine, which should be consistent at an individual system level, to reduce impact on staff working across multiple vaccination sites. If co-administration is being considered, then there should only be one type of flu vaccine and one type of COVID-19 vaccine at any time; dual and single vaccine clinics must be separated.

A <u>safety huddle checklist</u> and a <u>right vaccine checklist</u> (covering primary courses and 3rd primary courses and boosters) have been shared previously to support sites with reducing risk and ensuring the right vaccine is administered.

12. End of Phase 1 and 2 COVID-19 vaccination Enhanced Service and Local Enhanced Service on 31 October 2021

Providers who are signed up to the phase 1 and 2 COVID-19 vaccination ES / LES and not the Phase 3 ES / LES will not be able to vaccinate any patients beyond 31 October 2021 (including any outstanding second doses). Site closure activity will commence from Monday 1 November. Further information will be shared with these sites shortly. We would like to extend our thanks to Phase 1 and 2 sites that are not participating in Phase 3 for their contributions to the COVID-19 vaccination programme.

13. Workforce and Training updates

A. Local registered and unregistered Landmark candidates are now available through your Lead Employer

Landmark is a COVID-19 legacy programme which supports individuals who came forward to assist the pandemic response but have not been to secure a long-term NHS role. We have a number of bank and substantive candidates who are now ready to be deployed into your workforce and can help address your current vacancies.

To date, we have successfully placed some 100 candidates and we have around 4,200 registered healthcare professionals and 800 unregistered individuals ready to be deployed across the country. Examples include:

- Registered Candidates include Band 5 and 6 Nurses; Physiotherapists;
 Occupational Therapists; Podiatrists; Dental Hygienists.
- Unregistered candidates include staff for estates and facilities; administrative staff who can fill roles to support elective recovery and potential staff for 111 call centres. Interested? Contact your <u>lead employer</u> for more details, including who is available in your area and the process for accessing this staff, as well as our handy FAQs flyer and Futures NHS page.

B. Royal Voluntary Service (RVS) Volunteer Stewards – now available in vour area

Following a decline in volunteer availability over the summer months, we are now observing an increase in RVS volunteer availability and shift fulfilment and encourage systems and sites who may be using other providers or be employing paid stewards, to now re-engage with the RVS volunteers.

RVS remains a critical supplier of stewarding support to the programme. Primarily employed at vaccination centres, they also support the programme across other settings, such as within local vaccination services (primary care networks, general practice, and community pharmacies). Recent RVS recruiting, including reaching out to corporate and sports bodies, students and other volunteer groups etc, provides RVS with an increasingly blended stewarding workforce that is deployable through the NHSVR GoodSam digital platform.

As we enter the winter months, and programme activity levels again increase, we need to make every volunteer count, for them to be gainfully employed, to feel appreciated and to remain committed. Your active engagement, and reengagement, of RVS stewards will contribute to optimising your workforce availability, capacity and resilience at this critical time.

Please contact your <u>lead employer</u> to see how you can access available RVS Steward Volunteers in your area and refer to the short <u>RVS webinar</u> on volunteer experience, which gives sites some handy top-tips on how they can best support their volunteers.

Please see the attached link for requesting Steward Volunteers https://future.nhs.uk/CovidVaccinations/view?objectId=866035

14. Help improve the vaccination recording experience

The NHS Vaccines Programme needs your help to understand your experiences of recording vaccinations at your site.

The survey takes approximately 3 minutes to complete and your help will allow us to learn about the needs of people using the service and how it can be improved.

Interested in taking part? Please complete this survey.