Regional Clinical Advice Response Service 19/03/21

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

Contents:

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MHRA Statement on AstraZeneca Vaccine

Following suspensions by some countries of the COVID-19 Vaccine AstraZeneca over suspected blood clots, the MHRA confirms that the benefits of the vaccine in preventing COVID-19 far outweigh the risks. People should still go and get their COVID-19 vaccine when asked to do so.

Please read the full statement below:

https://www.gov.uk/government/news/uk-regulator-confirms-that-people-should-continue-to-receive-the-covid-19-vaccine-astrazeneca

Vaccine Availability and Constraints - Update

From the week commencing 29 March, volumes for first doses of vaccines will be significantly constrained. This will continue for a four-week period due to national inbound levels and is in line with supply available to countries across the world.

Therefore, **all calendars across all sites on the National Booking Service (NBS) for 1- 30 April have now been locked.**

This means patients are unable to book new appointments for first or second doses during this time. Further information on next steps will be issued shortly.

All existing booked appointments will remain in place in appointment calendars and patients will be able to cancel these appointments if necessary. All open booking slots will remain available to book up to 1st April. Our focus must remain on vaccinating those in cohorts 1 – 9 and delivering second doses.

Please note the following:

- All sites should ensure that booking slots are opened to the full capacity of the increased vaccine allocation in the current period up to 30th March including utilisation of supply carried forward from previous weeks.
- Ensure use of all short life supply by 30th March.
- For those vaccination centres and community pharmacy-led sites with local booking systems (LBS) in place, action must now be taken to close all first and second booking slots not already filled with immediate effect for the same period 1-30th April.

Please do not attempt to create any new appointment availability between 1-30 April.

To ensure supplies can meet existing appointments arranged via NBS and LBS, the national team will be following up on the recently issued vaccination centre LBS sitrep to confirm existing bookings in this period. Community pharmacy-led sites will also be asked to confirm any such bookings shortly.

Thank you for your continued commitment and adaptability in ensuring that working together we make the best use of the significant volumes of vaccine up to the end of March and the reduced volumes now expected in April. Further guidance and communication will be issued to the NHS system and stakeholders later today.

Press Statement Regarding Safety of AZ Vaccine

Safety of AZ following reports of its use being suspended in some countries

We are aware that some countries have temporarily suspended use of the Oxford/AstraZeneca vaccine.

The AstraZeneca vaccine has been rigorously tested by the UK medicines regulator (the Medicines and Healthcare products Regulatory Agency, MHRA), the European Medicines Agency and the World Health Organisation for safety and efficacy. The UK has administered

11 million doses of AstraZeneca vaccine and there has been no demonstrable difference in the number of blood clots since the vaccine was introduced.

The benefits of the AstraZeneca Covid-19 vaccine outweigh any risks and people should still go and get their COVID-19 vaccine when asked to do so.

All vaccines that are available have been approved because they pass the MHRA's tests on safety and efficacy, so people should be assured that whatever vaccine they are given will be highly effective and protect them from coronavirus.

Due to the nature of vaccine supply combined with the evidence that all the available vaccines are safe and effective, it is not possible for individuals to choose which vaccine brand they receive.

JCVI Advises Prioritising Homeless People and Rough Sleepers for COVID-19 Vaccine

Many people who are homeless or sleeping rough are likely to have underlying health conditions which would place them in priority group 6. These are likely to be under-diagnosed or not properly reflected in GP records.

Due to current restrictions, many thousands of people who sleep rough have been housed in emergency accommodation. This provides a unique opportunity to offer vaccination to those often unable to access basic healthcare.

The Joint Committee on Vaccination and Immunisation (JCVI) advises that local teams consider a universal offer to adults experiencing homelessness and rough sleeping alongside those in priority group 6.

They should also be offered the vaccine without the need for an NHS number or GP registration.

Local decisions should be taken on whether a shorter schedule may be offered if they are unlikely to return for the second dose at 12 weeks.

Operationally, it is anticipated that the Oxford-AstraZeneca vaccine will be easier to deploy to this group of people. The optimal timing for the second dose of the Oxford-AstraZeneca vaccine is 8 to 12 weeks after the first dose.

Read the full press release here

Read the JCVI letter here

COVID-19 Guidance: Vaccines When Given in Pregnancy

Guidance on the safety of COVID-19 vaccines when given in pregnancy has been published (17.03.21). It is designed for health professionals to share with women who were vaccinated before they knew they were pregnant. All guidance for members of the public, as well as for people in clinical and non-clinical settings, is published and updated regularly on the GOV.UK collection page.

Covid vaccine in pregnancy

There is no known risk with giving inactivated virus or bacterial vaccines or toxoids during pregnancy or whilst breast-feeding. However, the COVID-19 vaccines have not yet been tested in pregnancy, so it has been advised that until more information is available, pregnant women should not routinely have these vaccines. As a matter of caution, COVID-19 vaccine is therefore not routinely advised in pregnancy but there are some circumstances in which the potential benefits of vaccination are particularly important for pregnant women. This may include women who are at very high risk of catching the infection or those with certain medical conditions that put them at high risk of suffering serious complications from COVID-19 infection. In such circumstances, a woman may choose to have COVID-19 vaccine in pregnancy following a discussion with her doctor or nurse.

If a COVID-19 vaccine is given to a pregnant woman, she should be reassured that the vaccine does not contain live SARS-CoV-2 virus and therefore cannot cause COVID-19 infection in her or in her baby. Some COVID-19 vaccines contain a different harmless virus to help deliver the vaccine – this virus cannot reproduce and so will not cause infection in a pregnant woman or her baby.

Evidence so far reviewed by the Medicines and Healthcare products Regulatory Agency (MHRA), the UK regulatory agency responsible for licencing medicines including vaccines, has raised no concerns for safety in pregnancy.

The data for each licensed COVID-19 vaccine in pregnancy is limited because pregnant women are not included in vaccine trials. This is not because of any specific safety concerns but as a matter of caution, like that applied to trials of most other medicines.

If a woman finds out she is pregnant after she has started a course of vaccine, she may complete vaccination during pregnancy if she is considered at high risk. Alternatively, vaccination should be offered as soon as possible after pregnancy.

COVID-19 disease in pregnancy

Available evidence suggests that COVID-19 infection in pregnancy is unlikely to lead to problems with a baby's development and there have not been any reports of this. There is also no evidence of an increased risk of miscarriage if you become infected during pregnancy.

There is some evidence that babies can be born prematurely to women who are very unwell with coronavirus [footnote 1]. In a UK study of pregnant women with COVID-19 disease serious enough to require hospital admission (most infected in the second or third trimester), only 6 of 265 babies tested positive for COVID-19 immediately after birth. In line with other studies, this suggests it is uncommon for the natural infection to pass from a woman to her baby. When babies have developed COVID-19 soon after birth they have been well.

The UK Vaccine in Pregnancy surveillance programme

All COVID-19 vaccines given inadvertently (that is, where the woman did not know she was pregnant at the time of vaccination) from the first day of last menstrual period to any time in pregnancy should be reported to the UK Vaccine in Pregnancy surveillance programme run by the Immunisation Department of Public Health England.

The objectives of the UK vaccine in pregnancy surveillance are to compile additional information on women who are immunised with specified vaccines whilst pregnant to monitor

the safety of such exposures. This data will be used to help better inform pregnant women who are immunised, their families and health professionals who are responsible for their care.

This surveillance is being undertaken in collaboration with the MHRA, the UK teratology information service (UKtis) and with Public Health Scotland, Public Health Wales and Public Health Agency in Northern Ireland.

Footnotes:

1. Knight Marian, Bunch Kathryn, Vousden Nicola, Morris Edward, Simpson Nigel, Gale Chris et al. Characteristics and outcomes of pregnant women admitted to hospital with confirmed SARS-CoV-2 infection in UK: national population based cohort study BMJ 2020; 369:m2107

Incomplete Vaccination Course and Vaccinating with Alternative Vaccine Types – Updated Guidance.

As the numbers of people vaccinated expands and we start to move into providing substantial numbers of second doses we are beginning to see increasing numbers of instances when it may not be straightforward to complete the vaccination with the same type of vaccine the patient had as their first dose.

The Green Book allows for a second dose with an alternative vaccine. However, this is intended to allow courses to be completed in exceptional circumstances and is not intended to encourage this as part of routine programme delivery. The key principle, that the second dose should be the same as the first, is in italics with the recommendation for action which can be considered where it is not possible to complete the course using the same vaccine, in bold.

The Green Book states:

Previous incomplete vaccination

If the course is interrupted or delayed, it should be resumed using the same vaccine but the first dose should not be repeated. There is no evidence on the interchangeability of the COVID-19 vaccines although studies are underway. Therefore, every effort should be made to determine which vaccine the individual received and to complete with the same vaccine. For individuals who started the schedule and who attend for vaccination at a site where the same vaccine is not available, or if the first product received is unknown, it is reasonable to offer one dose of the locally available product to complete the schedule. This option is preferred if the individual is likely to be at immediate high risk or is considered unlikely to attend again. In these circumstances, as the vaccines are based on the spike protein, it is likely the second dose will help to boost the response to the first dose. For this reason, until additional information becomes available, further doses would not then be required.

Examples:

1. A patient who had their first vaccination with Pfizer in hospital, is now residing in a nursing home. They would need to agree to be taken to a vaccination centre in order to complete their vaccination with Pfizer, if this is not wanted or not possible they, or someone able to make an informed choice or their behalf, could choose for them to be vaccinated on-site with the Astra-Zeneca vaccine. In most cases this latter option will be most practical

2. A patient attends a vaccination clinic for vaccination and their first dose vaccine is not available but there is time within the 12 week vaccine window and anticipated vaccine availability, to complete the course with the same vaccine they may:
    a) return for a 2nd dose with same vaccine
    b) be vaccinated with the available vaccine after appropriate informed consent is obtained if it is considered that they are unlikely to return to complete the vaccination course, or if they are at immediate high risk

3. A patient attends a vaccination clinic for vaccination and their first dose vaccine is not available and is not anticipated to become available in a reasonable timescale i.e. to maintain as near as possible the 12 week dose interval and enable them complete the course with the same vaccine. In this situation, a risk / benefit assessment should be undertaken, and the patient may be advised to complete the course with the available vaccine.

NOTE:

- The reactivity and efficacy of mixed schedules are currently not known, and it is therefore important to ensure that reactions related to mixed schedules and / or infections occurring post vaccination are accurately reported to CARS (england.swcovid19-voc@nhs.net) and to the MHRA via the Yellow Card system.

- The second dose of vaccine can be given under PGD, even within mixed schedules, as all current COVID19 vaccines are authorised under Section 174. The national PGDs are currently being revised and this will be made more explicit in future versions.

- When a patient receives a different second vaccine dose to their initial vaccine to complete their schedule it is important to ensure that informed consent is obtained and the rationale for the decision is fully documented.

Consent within the Vaccination Process. Clinical Workstream: National Covid Vaccination Programme

What consent is needed?

Consent must be obtained before starting any treatment or physical investigation or before providing personal care for a patient; this is standard NHS practice and is a legal requirement. Consent also needs to be checked **each** time a patient has any type of medical treatment, test or examination.

This applies to administration of all vaccines including COVID-19 vaccinations. Consent to treatment means a person must give permission before they receive any type of medical treatment, test or examination.

For consent to be valid, it must be given voluntary by an appropriately informed person who has the capacity to make the decision.

If an adult with capacity makes a voluntary and appropriately informed decision to consent to or refuse a COVID-19 vaccination, their decision must be respected and documented. A person with capacity is entitled to withdraw consent at any time, including during the performance of a procedure.

If the person has made a valid and applicable Advanced Decision (i.e. witnessed, in writing, and stating that it applies even if their life is at risk) to refuse all vaccines, or specifically to refuse the COVID-19 vaccine, then this must be followed.

Immunisation against Infectious Diseases Chapter 2 provides guidance on the consent process for vaccinations and in this regard delivery of COVID-19 vaccination.

Best practice includes offering as much information as the patient reasonably needs to make their decision, including the anticipated benefits and material risk of vaccination, the likely side effects from vaccination and any individual risks they may run should be addressed, and the disbenefits of not consenting to the vaccination in a form that they can understand.

Consideration will need to be given to the type of information the patient receives, this includes information in other languages or easy read leaflets.

What if a patient cannot give consent?

Where a person aged 16 or over lacks the capacity to give consent, no one can give consent for that person unless they have relevant authority under a Lasting Power of Attorney for Health and Welfare (LPA) or have been authorised to make treatment decisions as a Deputy appointed by the Court of Protection (Deputy).

A decision to vaccinate may be made and treatment may be given in the incapacitated person's best interests in accordance with the Mental Capacity Act 2005 (MCA).

Best interests decisions must always be made on an individual basis. The best interests decision-maker (the registered healthcare professional) must consider all the relevant circumstances, including the person's wishes, beliefs and values and the views of their family / carers, where appropriate, as to what the person would have wanted if they had the capacity to make the decision themselves. Discussions with family members/carers should begin early, and preparations made for a 'best interests' decision to be made in line with the best interests checklist in section 4 of the MCA.

Who must obtain consent?

Consent must be obtained by a registered health professional. The national protocol specifies which healthcare professionals can undertake the clinical assessment and consent process. Those involved in obtaining consent must be competent to carry out the task. The registered professions specified and/ the prescriber should ensure that the person (or those with authority to give consent on their behalf) fully understands which immunisation(s) are to be administered; the disease(s) against which they will protect; the risks of not proceeding; the side effects that may occur and how these should be dealt with; and any follow-up action required. It is the healthcare professional who decides whether the person has the capacity to make that decision.

Whilst other staff can support the process, by providing information (often in advance) or with pre-screening i.e. asking questions in advance, the ultimate decision on whether valid consent has been given with the registered healthcare professional.
Does consent need to be written?

Those who can give consent may do so in writing, orally or by co-operation. There is no legal requirement for consent to the vaccination to be in writing ,however the consent process and

any decision must be documented to serve as a record of the decision and the discussions that have taken place with the person or in relevant case the person giving consent on their behalf (an LPA or Deputy with relevant authority).

Is consent needed for second doses?

Consent needs to be obtained for each dose of Covid vaccination given. As the previous consent was undertaken 12 weeks ago this is sufficient time for changes with the patients' health status, therefore the patient will need to be re-assessed and they should have the opportunity to ask any further questions relating to the second dose such as any side effects.

What is pre-screening?

Pre-screening is the process of asking a key set of clinical questions that have a yes or no response. These questions can be asked by a non-registered staff member to support the consenting and clinical assessment process or these questions could be electronic, and the patient could respond to these questions themselves. Whilst non-registered staff are able to ask questions on behalf of the registered healthcare professionals, they cannot carry out the clinical assessment or consent process for the patient. The registered healthcare professional must review the screening information as part of the consent process.

Can patients be consented in advance?

Patients can be pre-screened in advance however valid consent must be obtained on the day of vaccination; this can be a verbal check. On the day the registered healthcare professional must make sure that consent is voluntary, that the patient has had sufficient information to give consent and that the patient has capacity to give consent.

Does an additional consent form need to be filled in for care home residents for second doses?

When a resident has given valid consent to receive the full course of vaccination (or consent is given on their behalf by an LPA or Deputy with relevant authority), in general that consent remains valid unless it is withdrawn by the person. As the consent from was completed 12 weeks ago, the registered health care profession should check with the person who has given consent (assuming they retain capacity) that they still wish to proceed with the second vaccination. The ultimate decision on whether valid consent has been given with the registered healthcare professional administering the vaccination.

If a resident has been assessed to lack capacity to consent to the vaccination and a decision has been made on best interests, in line with the best interests checklist in section 4 of the MCA the registered healthcare professional should confirm if the best interest decision relates to the full course of the COVID-19 vaccination and if so a second consent form may not need to be completed. However, at the time of administration of the second dose, the healthcare professional administering the vaccine must be satisfied, through personal clinical assessment, that the person lacks capacity to make a decision about being vaccinated and that the vaccination is in their best interests.

How do I consent patient cohorts outside of the MHRA approved conditions of authorisation?

Where vaccination is being offered outside of the conditions for authorisation (for example children aged 12-16 with severe neuro-disabilities that require residential care), the consent,

clinical assessment and risk benefit discussion must be carried out by a prescriber, usually a doctor. As in the case for adults, valid consent will normally be required before any treatment can lawfully be given to a child aged under 16. Consent may be given by a competent child, by any person who has parental responsibility for the child or by the court. Where a child under 16 is not competent to give consent, consent can be given on their behalf by any one person with parental responsibility. Clinicians should discuss the risks and benefits of vaccination with a person with parental responsibility, who should be told about the paucity of safety data for the vaccine in children aged under 16 years.

Vaccine Storage and Fridges in GP practices – Data Loggers

In order to keep vaccines safely and correctly stored, we recommend that GP practices should have a data logger. They allow you to gain more detailed information about the fridge temperature if there is a cold chain failure, for example a power cut.

Please use the following links to explore this issue further:

Nigel's surgery 17: Vaccine storage and fridges in GP practices | Care Quality Commission (cqc.org.uk)

Green_Book_Chapter_3_v3_0W.pdf (publishing.service.gov.uk)

Protocol for ordering, storing and handling vaccines - GOV.UK (www.gov.uk)

COVID-19: Vaccinator Competency: Knowledge and Skills Competence Assessment Tool.

The PHE COVID-19 vaccinator competency assessment tool has been published to enable the assessment of an individual against specific vaccines (where relevant for particular competencies).

An additional competency has been added for dilution (currently Pfizer only).

There are blank rows for additional vaccines to be added in locally as they come online (where relevant).

https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool

Resource to Support Conversations Regarding Vaccine Hesitancy

Resources have been produced following a behavioural insights study across Leicester City, Leicestershire & Rutland (LLR). The work was led by local authority public health colleagues working jointly to produce a conversation tool and additional resources to support conversations between managers and staff to talk about vaccine hesitancy and some of the myth busting. The principles that underpin the tool are adapted from the Wessex MECC approach.

The tool can be accessed at the following link:

www.healthyconversationskills.co.uk/vaccineconfidence

Query Routes for Vaccination Sites

Please find attached a resource to aid you in directing and finding answers to your vaccination programme related queries.

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