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Dear Colleagues

COVID-19 VACCINATION PROGRAMME

This letter provides a further update on the delivery of the COVID-19 vaccination programme.

I recognise the tremendous progress that has already been made by Health Boards in delivering the vaccination programme at such pace, and I am grateful to you for your continued hard work and dedication in ensuring we protect those most at risk from COVID-19.

Key Objectives

1. To confirm a change in recommended use of the AstraZeneca vaccine following further advice from the Joint Committee on Vaccination and Immunisation (JCVI).

2. To further clarify the Medicines and Healthcare products Regulatory Agency (MHRA) steer and the JCVI guidance on those at rare risk of blood clots associated with the AstraZeneca Vaccine.

3. To confirm the final JCVI Phase 2 advice for vaccinating those under 50 years old.

4. To provide an update on vaccination of pregnant women.

5. To confirm inclusion of adult household contacts of severely immunosuppressed adults alongside cohort 6.

6. To update and clarify operational guidance around particular aspects of the vaccination programme.

Change in recommended use of AstraZeneca

7. The JCVI has today published updated advice on the recommended use of the AstraZeneca vaccine. This is further to its advice published on 7 April advising that adults under the age of 30 who are not in a clinical priority group should be offered an alternative vaccine, where possible.

From Chief Medical Officer
Chief Nursing Officer
Interim Chief Pharmaceutical Officer
Dr Gregor Smith
Professor Amanda Croft
Professor Alison Strath

07 May 2021

SGHD/CMO(2021)11

Addresses
For action
Chief Executives, NHS Boards
Medical Directors, NHS Boards
Primary Care Leads, NHS Boards
Directors of Nursing & Midwifery, NHS Boards
Chief Officers of Integration Authorities
Chief Executives, Local Authorities
Directors of Pharmacy
Directors of Public Health
General Practitioners
Practice Nurses
Immunisation Co-ordinators
Operational Leads

For information
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8. The JCVI has continued to review the data in relation to the link between AstraZeneca and Vaccine Associated Thrombosis and Thrombocytopenia Syndrome (VATTS). Based on the latest information available, they have recommend offering an alternative vaccine where possible to those aged 30 to 39 years old who have not yet been vaccinated, and who have no underlying health conditions, within the Phase 2 cohorts where no substantial delay or barrier to vaccination would arise.

9. The JCVI has advised that vaccination of adults aged 30-39 years with any of the UK authorised vaccines is always better than no vaccination, except where there are specific contraindications. Therefore, operational flexibility is advised particularly for those under 40 years who are of older age, male, obese (BMI >30), from certain ethnic minority backgrounds or experiencing socio-economic deprivation, the risks of acquiring and/ or suffering complications of COVID-19 are higher. Every effort should be made to remove barriers to accessing vaccination in those individuals.

10. The JCVI also advises that everyone who has already had a first dose of AstraZeneca should receive a second dose from the same manufacturer, regardless of their age, except for a very small group of people who have experienced blood clots with low platelet counts after their first dose of vaccine or have experienced a severe allergic reaction to their first dose. Individuals offered a COVID-19 vaccine should be fully informed about the benefits and risks of vaccination and as such, individuals may make an informed choice to receive the AstraZeneca vaccine

11. The clear scientific evidence and advice continues to be that the benefits of receiving the AstraZeneca vaccine far outweigh the risks for most age groups by providing protection against the harm of COVID-19. It remains critical that people continue to come forward to receive second doses of the vaccine to ensure optimal sustained protection from vaccination.

Further clarity following MHRA and JCVI advice

12. On 7 April I wrote to you addressing the additional safety advice the MHRA issued in regards to the potential link between the AstraZeneca vaccine and extremely rare blood clots. Subsequently, the Green Book has been updated to include information on instances of thrombosis and thrombocytopenia occurring after vaccination with AstraZeneca.

13. As per the Green Book, there is no current evidence of any underlying risk factors in the individuals affected by this condition who have mainly been previously healthy. The condition is rare, tends to present with unusual forms of clotting and the mechanism is believed to be an idiosyncratic reaction related to an immune response to the AstraZeneca vaccine. Because of this likely immune mechanism, there is no reason to believe that individuals with a past history of clots or of certain thrombophilic conditions would be at increased risk of this very rare condition.

14. Similarly, although pregnancy increases the risk of clotting conditions, there is no evidence that pregnant women, those in the post-partum or women on the contraceptive pill are at higher risk of the specific condition of thrombosis in combination with thrombocytopenia after the AstraZeneca vaccine. There have been no confirmed cases reported in pregnant women to date.

15. The contra-indications to vaccination with the AstraZeneca COVID-19 vaccine have now been amended to include individuals who have a history of a previous episode of

heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2). These individuals may be offered vaccination with an alternative COVID-19 vaccine.

16. The Green Book advises that individuals who experience clotting with concomitant thrombocytopenia following the first dose of AstraZeneca should be properly assessed. If they are considered to have the reported condition, further vaccination should be deferred until their clotting has completely stabilised, and an alternative vaccine should be considered for their second dose. Individuals who have received the first dose of AstraZeneca without developing this rare condition are advised to receive the second dose of the same vaccine.

17. There is no evidence that those with a prior history of thrombosis or known risk factors for thrombosis are more at risk of developing this immune-mediated condition of thrombosis in combination with thrombocytopenia after the AstraZeneca vaccine. For most of these individuals, the risk of recurrent thrombosis due to COVID-19 infection, remains far greater than the risk of this syndrome.

18. Therefore individuals with such a history should be vaccinated with any of the available vaccines (provided they are not otherwise contra-indicated).The same consideration applies to those who experience common clotting episodes after the first dose of AstraZeneca vaccine but without concomitant thrombocytopenia. The updated protocol and Patient Group Direction (PGD) will be circulated in due course.

Final Phase 2 JCVI advice

19. The independent JCVI published a statement on Phase 2 of the COVID-19 vaccination programme on 13 April. Following the successful delivery of Phase 1 of the programme, the JCVI has formulated final advice which sets out the most effective way to minimise hospitalisations and deaths. In line with its interim advice, the JCVI has recommended an age-based approach with adults aged 18-49 prioritised in descending age order as follows:

- All those aged 40-49 years
- All those aged 30-39 years
- All those aged 18-29 years

20. The JCVI recognises that progressing into Phase 2 should be alongside continued efforts to those prioritised in Phase 1 who remain unvaccinated, and completion of delivery of second doses to those vaccinated in Phase 1. Whilst there is operational flexibility in including other cohorts concurrently, this should not be at the expense of earlier cohorts. I would encourage Health Boards to call those newly identified, or yet unvaccinated, in Phase 1 as a matter of priority before those in Phase 2.

21. Data indicate that in individuals aged 18 to 49 years there is an increased risk of hospitalisation in males, those from certain minority ethnic backgrounds, those with a BMI of 30 or more (obese/morbidly obese), and those experiencing socio-economic deprivation. The JCVI strongly advises that individuals in these groups promptly take up the offer of vaccination when they are offered, and that deployment teams should utilise the experience and understanding of local health systems and demographics, combined with clear communications and outreach activity to promote vaccination in these groups. The JCVI supports flexibility in delivery of the programme to ensure maximum uptake.

22. Individuals who are at increased risk of severe outcomes from COVID-19 are likely to be vaccinated most rapidly by an operationally simple vaccine strategy. JCVI will continue

close monitoring of the programme in terms of safety, effectiveness and uptake, and will update its advice as required.

Advice on vaccination for pregnant women

23. Based on new data which shows no safety concerns in around 90,000 pregnant women who were vaccinated, the JCVI advises women who are pregnant should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group. The data from the study in the United States involved mainly mRNA vaccines, including Pfizer-BioNtech and Moderna.

24. Therefore, the JCVI advises that it is preferable for pregnant women in the UK to be offered Pfizer or Moderna vaccines where available. Women who have already received their first dose of the AstraZeneca vaccine should continue with AstraZeneca for their second dose. Healthcare professionals offering COVID-19 vaccination to pregnant women should continue to discuss the benefits and risks, this should include discussion of the vaccine types available and side-effects, including the extremely rare adverse thrombotic events. The Green Book has been updated with this advice, available here: Greenbook chapter 14a (publishing.service.gov.uk).

25. All communication materials targeting pregnant women including the pregnancy leaflet have been updated with links provided to the risk-benefit information contained in the Royal College of Obstetricians and Gynaecology (RCOG) website.

Identification of households living with severely immunosuppressed people

26. As there is now data indicating the potential for a reduction in transmission in those vaccinated, the JCVI advises that adult household contacts of adults with severe immunosuppression are offered COVID-19 vaccination alongside priority group 6. This will help reduce the risk of infection in those who may not be able to fully benefit from being vaccinated themselves. The JCVI advises that a reasonable definition of household contacts would be individuals who expect to share living accommodation on most days and therefore for whom continuing close contact is unavoidable.

27. The JCVI has not provided a definitive list within their advice of those individuals classed as having severe immunosuppression. Furthermore, immunosuppression is a continuum, and sometimes transient, clinical state due to a variety of clinical reasons from mild, moderate to severe. There are no coding systems in place that distinguish clearly from severe immunosuppression state to moderate state as individuals can move from one state to the other at any one point in time depending on a range of factors, for example the treatment they are on.

28. The Green book states that the more severely immune-suppressed individuals within the wider immunosuppression group should already be flagged as Clinically Extremely Vulnerable (CEV) and, as such, will be included on the shielding list.

29. As a result of the difficulties of accurately identifying those individuals at the severe end of the immunosuppression scale, and as they will be included within the shielding list due to their being CEV, the decision has been made to extend the offer of vaccination to the adult households of all adults on the shielding list.

30. Using the shielding list in this manner ensures that we do not miss severely immunosuppressed adults who can't otherwise be identified, as well as also including other

CEV individuals from the shielding list who are likely to benefit from having the same household protection. Letters are due to be sent to those on the shielding list advising that their eligible adult household contacts who have not yet had the vaccine are to contact the National Vaccination Helpline

Further operational guidance

31. Delivering a mass vaccination programme does not come without its challenges and complexities and this is why we must ensure operational flexibility which includes minimising vaccine wastage. At the end of January, the Chief Pharmaceutical Officer provided guidance to Health Boards within the context of the JCVI guidance to support Health Boards in maximising use of available vaccine. The guidance is available at **Annex A.**

32. Following on from the CMO letter dated 5 February, Health Boards are reminded that wherever practicable, vaccinations should be offered to patients who are rehabilitating (i.e. recovering after the acute state of the illness that caused their hospitalisation) or who are deemed to be “long-stay”, including those in mental health wards, in line with cohorts already being offered vaccination in the community.

Action

33. Health Boards are asked to note and implement the arrangements for the COVID-19 vaccination programme outlined in this letter.

34. It is crucial that individuals continue to come forward for vaccination when invited to do so. I am grateful for Health Boards’ continued efforts to offer information, support and encouragement to those invited for vaccination so that public confidence in this critical programme remains high.

Yours sincerely,

Gregor Smith	*Amanda Croft*	*Alison Strath*
Dr Gregor Smith **Chief Medical Officer**	Professor Amanda Croft **Chief Nursing Officer**	Professor Alison Strath **Interim Chief Pharmaceutical Officer**

GUIDANCE ON MINIMISING VACCINE WASTAGE

Some vaccine wastage is unavoidable for a variety of reasons based on the characteristics of the vaccine, logistical issues with cold chain supply, storage failure, vial size and/or specific clinical situations but there are steps that can be taken to minimise the risk of waste.

Best practice to avoid wastage

Clinic Planning

- Vaccination clinic appointment numbers should be planned taking into consideration the maximum number of doses possible to be extracted from a vial in order to make maximum use of available vaccine
    - 6 doses from a vial of the Pfizer vaccine (there must be sufficient to extract a full 0.3 mL dose). Where a full 0.3 mL dose cannot be extracted, the remaining volume should be discarded
    - 11 doses or 9 doses from the 10-dose or 8-dose multi-dose vials of the AZ vaccine respectively (there must be sufficient to extract a full 0.5 mL dose). Where a full 0.5 mL dose cannot be extracted, the remaining volume should be discarded.
- A contingency plan should be put in place to manage the risk when less vaccine than expected is used during a clinic. Examples include maintaining a reserve list to ensure vaccine is not wasted (e.g. care home or front line health and social care staff or second doses). Ideally this should be from within the same cohort however the JCVI has also indicated that there should be some flexibility in including other cohorts concurrently e.g. those age 75 years and over **but not at the expense of earlier cohorts**, particularly care homes. A bundling approach has been agreed for the Island Health Boards and for cohorts 3, 4 and 5.
- If the remainder of the vaccine is in un-punctured vials, which are still in the fridge, consider whether subsequent orders can be reduced.
- Be aware of local arrangements with other immunisation services who would be able to utilise the spare vaccine within short notice.
- Ensure there is enough needle and syringe supplies.
- While at this stage there is little known with regard to projected uptake and attendance rates, scheduling teams and planners should liaise to monitor this closely in order to ensure the pharmacy is supplying an optimal number doses and maximising the use of the supply chain.

At the clinic

- Good oversight and management in vaccination clinics and centres is essential, especially when there are multiple immunisers, and is key to avoiding multiple immunisers each with unused doses.
- Ensure any unused vaccine is used within six hours of the multi-dose vial being punctured.
- Use the combined needle and syringes provided with the vaccine, wherever possible. These are dose-sparing (low dead space) combined needles and syringes and will help optimise the number of doses that can be extracted from a vial.
- If there is any evidence that the vaccine has been stored incorrectly, label and isolate the affected vaccine in the fridge and seek advice as soon as possible in line with locally held procedures, for example contact the Vaccine Holding Centres or your

immunisation coordinator. Depending on the specific circumstance, the vaccine may still be acceptable for use.
- Whilst reducing waste is important, if using any additional dose in a vial, then this must come from one vial and a dose should **never** be made up from wastage in multiple vials

Continual Learning and Process Improvement

- All wastage should be reviewed locally and at Health Board level to ensure any preventable loss is avoided in the future
- A web-based vaccine waste recording tool has been developed on the Service Now platform and is available for use. It enables vaccinators to record any vaccine wastage produced at any Covid-19 vaccine clinic. It has been developed primarily to record the number of wasted doses along with the reason they were wasted to help understand common reasons for vaccine wastage to support identifying actions that can be taken to reduce waste.
- Significant wastage should be treated as a serious adverse event to ensure learning is applied.