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From Chief Medical Officer
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Dear Colleagues

COVID-19 VACCINATION PROGRAMME: UPDATE

1. This letter updates on the arrangements for the COVID-19 vaccination programme, following authorisation for supply and use of the AstraZeneca COVID-19 vaccine and changes to advice on the use of the Pfizer BioNTech vaccine by both the Medicines and Healthcare products Regulatory Agency (MHRA) and the Joint Committee on Vaccination and Immunisation (JCVI).

2. I am grateful to you for your hard work in ensuring a successful beginning to the COVID-19 vaccination programme, despite the complex challenges posed by the particular requirements associated with the Pfizer BioNTech vaccine. I also appreciate that you are delivering this vaccination programme across the winter period and more importantly across a range of public holidays for which I am deeply grateful.

3. The programme remains a critical part of our work to reduce the impact of COVID-19 on those most at risk. Effective planning and delivery of the programme is essential to protect those most at risk, prevent ill health in the population and minimise further impact on the NHS and social care services.

Key Objectives

4. To commence rollout of the AstraZeneca vaccine from 4 January 2021 and continue roll out of the Pfizer BioNTech vaccine, in line with JCVI advice and prioritisation and the additional guidance on prioritisation provided on 24 December 2020 (set out in Annex C).

5. To roll out the AstraZeneca vaccine from 4 January in existing vaccination settings, moving out into more community settings including GP practice settings from the 11 January. This does not preclude moving into community settings earlier than the 11 January.

6. To continue to protect those most at risk by achieving high vaccine uptake amongst the priority groups. It should be noted that the JCVI does not advise a preference for

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either vaccine in any specific population but notes that for operational and practical reasons, such as to enable more extensive and timely vaccine coverage, one vaccine may be offered in certain settings over another vaccine.

Timing of second doses

7. Following a review of the clinical evidence in relation to both the AstraZeneca and Pfizer BioNTech vaccines, the JCVI has recommended that first doses of vaccine are prioritised for as many people as possible on the Phase 1 JCVI priority list, in advance of second doses to provide more assured longer term protection.

8. This reflects the need to reach as many people in the shortest possible timeframe, within the available vaccine supplies, against a background of immediate disease activity and high population sero-susceptibility (despite the disease burden seen).

9. This is on the basis that the protection of vaccinees after the first in a two-dose schedule is very substantial. This evidence will be published by the JCVI and PHE.

10. This strategy is also strongly supported by the UK Chief Medical Officers and their Deputies.

11. All NHS Boards should therefore now take the following actions to ensure delivery is in line with the regulatory advice from the MHRA and the updated clinical guidance from the JCVI:

    • For recipients who have received their first vaccination and are due to receive their second dose between now and Monday 4 January 2021, no further action is required, and these appointments should continue as planned.

    • For those who have received their first vaccination and are scheduled to receive their second dose after Monday 4 January 2021, the second dose appointment should be rescheduled in the twelfth week post the first dose.

    • For those scheduled to receive their first vaccination from 31 December 2020, an appointment to receive the second dose should be scheduled in the twelfth week post the first dose.

12. Those services that will be operational from Monday 4 January 2021 onwards should to ensure that all second dose appointments are booked in the twelfth week post the first dose.

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13. I recognise that the requirement to re-schedule second appointments is operationally difficult in the short term and may be unpopular with patients booked in for a second dose in the immediate future.

14. However, for every 1000 people boosted with a second dose of covid-19 vaccine in January (who will as a result gain marginally on protection), 1000 new people would be delayed in receiving what amounts to very substantial initial protection which is in most cases is likely to raise them from 0% protected to at least 70% protected in typically 14-21 days.

15. This approach will therefore allow as many first doses as possible to be provided as quickly as possible, providing substantive levels of individual protection while reaching more of those most at risk.

Conditions of authorisation

16. The MHRA statement on AstraZeneca conditions has now been published.

17. The MHRA has also updated the conditions for the authorisation for the supply of the Pfizer BioNTech vaccine to remove the requirement to hold back 50 per cent of available doses for administration as second doses.

Phased Approach

18. We anticipate receiving up to 440,360 doses of AstraZeneca vaccine across January with deliveries beginning from 2 January 2021.

19. We anticipate that further doses will become available via regular delivery throughout early 2021.

20. A phased approach remains necessary. For the AstraZeneca vaccine, as for the Pfizer BioNTech vaccine, the intention is to provide an important layer of protection to all adults but particularly those most at risk from serious illness and death from COVID-19.

21. With age as the greatest risk factor, the JCVI has retained the same phase 1 priority list. (See Annex C).

22. The priority now is to vaccinate as many people with their first dose as quickly as possible, working through that priority list, and the advice that the second dose for both vaccines can be given up to 12 weeks after the first means that this protection can be maximised quicker than

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originally planned. **The second dose remains critical for longer term protection and to complete the course.**

Communication materials

23. Differences in vaccine characteristics between the AstraZeneca and Pfizer BioNTech vaccines, and adjustments to the JCVI advice about timing of second doses and eligibility, means that a careful communications approach is required.

Materials for staff

24. Separate communications toolkits for health and social care workers to be vaccinated have been available since the start of the programme in early December but will be updated to reflect the new advice as soon as possible and before 4 January. These toolkits are similar to those received for other immunisation programmes such as flu and will include staff posters, leaflets, emails and social media content to help you understand the importance of receiving the vaccine as a health or social care worker. These toolkits are available via the links below:
https://www.publichealthscotland.scot/covidvaccinehcw
http://www.publichealthscotland.scot/covidvaccinescw

25. Updated workforce education materials will be available on the Turas Learn site from 5 January. COVID-19 vaccines | Turas | Learn (nhs.scot)

26. .From 31 December 2020 staff will have access to the updated Green Book Chapter 14a and information for healthcare professionals on COVID-19 Vaccine AstraZeneca, online here: Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca - GOV.UK (www.gov.uk)

Materials for care homes

27. Consent packs for care homes are available to download here:
http://www.publichealthscotland.scot/covidvaccinecarehome

Materials for the public

28. Those aged 80 years and over will be invited to attend for vaccination by their local NHS Board/ GP practice via a letter and accompanying leaflet. Materials to allow GPs and NHS Boards to invite those aged 80 years and over will be available here as soon as possible and before January 4th :
https://www.publichealthscotland.scot/covidvaccinegp

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29. Hard copies of these leaflets will be printed and distributed to GPs / NHS Boards from January 6th. Further copies can be ordered at: phs.covidpublications@phs.scot

30. In later phases of the programme, other groups will be invited in due course in line with the JCVI prioritisation. A national scheduling tool is being built which will support the scheduling of further cohorts, this is being developed at pace and is on track for delivery by the end of January 2021.

31. This will be in addition to a national, local and sectoral public information campaign. There will be a national door drop during week commencing 4 January and a TV and radio campaign from 21st of January.

Key contact points

32. For more information, members of the public will be asked to visit Coronavirus (COVID-19) vaccine | NHS inform or call 0800 030 8013.

33. The COVID-19 vaccination helpline, for general information about the coronavirus vaccine and its delivery, is now available from 8am to 8pm, seven days a week on 0800 030 8013. It will not be possible to book or change vaccine appointments via the helpline at this stage.

34. The MHRA has advised that suspected side effects to medicines, vaccines, or medical devices used in COVID-19 treatment should be reported via the dedicated Coronavirus Yellow Card reporting site: https://coronavirus-yellowcard.mhra.gov.uk/

35. In addition, health boards should follow the Framework for reporting, monitoring and escalating adverse events in the COVID-19 immunisation programme' which covers the escalation to Public Health Scotland and the national COVID-19 vaccine clinical governance group. It is available online here: Reporting adverse events that occur during the COVID-19 immunisation clinic : guide for clinic staff | Turas | Learn (nhs.scot)

Resources

36. NHS Boards are asked to ensure immunisation teams are properly resourced to develop and deliver the COVID-19 vaccination programme, noting that additional costs will be met by the Scottish Government. The established financial allocation approach that is in place will support this process and should ensure that there are no barriers or delays to delivering this programme.

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37. As previously set out, work continues between SG Health Finance and Boards Directors of Finance to assess the financial implications of the activities and approach set out in this letter, which we expect will continue to develop, and from there financial allocations will be confirmed to Boards early next year. Any questions on the financial allocations process should be directed to Richard McCallum or Joe Welsh.

Action

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

39. Delivery should continue to reflect the service delivery framework, reflecting local delivery of the national plan for the programme.

40. It is critically important that every effort is made to ensure high uptake, and that those eligible to receive a vaccine do so. This is, of course, subject to supply of vaccine therefore ongoing and effective engagement and management at a local level is essential.

41. I am very grateful for your continued commitment and support in delivering the COVID-19 vaccination programme.

Yours sincerely,

Dr Gregor Smith
Chief Medical Officer

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ANNEX A: UPDATED PRIORITY GROUPS AND DELIVERY MECHANISMS

Cohort Prioritised	Rationale	Delivery Mechanism
Care Home Residents in Care Homes for Older Adults	JCVI and CMO Priority Cohort The most vulnerable to Covid	Vaccinate in Care Homes
Care Home Workers in Care Homes for Older Adults	JCVI and CMO Priority Cohort To protect staff in Care Homes with outbreaks, and to protect vulnerable residents	Vaccinate in Care Homes
Healthcare Staff working with direct face to face contact in health care settings. In view of limited vaccine availability, Boards should seek to vaccinate to cover: i)Vaccinators ii) Others based on a risk assessment taking into account factors such as those who are working in Covid red areas and age (older staff)	JCVI and CMO Priority Cohort Increased exposure to Covid Ensures that we can appropriately use vaccine available at NHS Board Vaccination Centres and minimise wastage.	NHS Board Vaccination Centres
Long stay inpatients aged Over 80	JCVI and CMO Priority Cohort Long stay inpatients similar vulnerability issues to Care Home Residents	NHS Board Vaccination Centres NHS Boards should ensure that they are also able to provide the second dose to this group
Over 80s in the community	JCVI and CMO Priority Cohort	Vaccinate via community settings/GP practices,

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ANNEX B COVID VACCINE: COMPOSITION, ORDERING AND DELIVERY ARRANGEMENTS, PATIENT GROUP DIRECTIONS

Oxford AstraZeneca Vaccine

The AstraZeneca COVID-19 vaccine is the second COVID-19 vaccine to be authorised for supply in the UK.

The vaccine uses a replication deficient chimpanzee adenovirus (ChAd) as a vector to deliver the full-length SARS-CoV2 spike protein genetic sequence into the host cell (Van Doremalen et al, 2020). ChAd is a non-enveloped virus, and the glycoprotein antigen is not present in the vector, but is only expressed once the genetic code within the vector enters the target cells. The vector genes are also modified to render the virus replication incompetent, and to enhance immunogenicity (Garafalo et al, 2020). Once the vector is in the nucleus, mRNA encoding the spike protein is produced that then enters the cytoplasm. This then leads to translation of the target protein which acts as an intracellular antigen.

Vaccine Composition

The AstraZeneca vaccine is supplied in packs of 10 vials. Each vial contains 8 or 10 doses of vaccine, and is a colourless to slightly yellow, clear to slightly opaque liquid.

Further detail is available here: Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca - GOV.UK (www.gov.uk)

Delivery arrangements

The vaccine will be delivered to authorised holding sites within Boards. Detailed information on the distribution arrangements including order-cut off times and delivery days has been shared with Health Boards. For support contact nss.fluvaccineenquiries@nhs.scot

Patient Group Direction

A national specimen Patient Group Direction (PGD) for administration by specified registered healthcare practitioners of the AstraZeneca COVID-19 vaccine has been developed and will become available at
https://www.hps.scot.nhs.uk/publications/patient-group-directions/

National Protocol

In order to ensure that there is a sufficiently sized workforce to deliver a COVID-19 vaccine programme, the changes to the Human Medicines Regulations (The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020), also brought about a new regulation (247A). While a disease is pandemic, regulation 247A permits the supply or administration of a medicinal product used for vaccination or immunisation against coronavirus in accordance with a protocol that is approved by ministers.

Such a national protocol may allow specified classes of people, which need not be limited to registered healthcare professionals, to administer COVID-19 vaccine. A national protocol is being developed by Scottish Government and will be made available shortly.

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ANNEX C JCVI PRIORITISATION, VACCINE ELIGIBILITY AND ADDITIONAL ADVICE

Prioritisation

Full details of the JCVI's prioritisation advice as published on 2 December can be found here: https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-2-december-2020

Further detailed guidance was provided on prioritisation on 24 December, as set out in the table below:

42. **JCVI Priority**	**Group**
1	**Residents and workers in care homes for older people.** Residents and those working in long-stay residential and nursing care homes or other long-stay care facilities for older adults where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. This includes non-clinical ancillary staff who may have social contact with resident but are not directly involved in patient care, such as cleaners and kitchen staff.
2	**all those 80 years of age and over** Starting for logistical reasons with long-term hospital inpatients who are over 80.
2	**Patient facing, frontline healthcare workers.** Staff who have frequent face-to-face clinical contact with patients and who are directly involved in patient care in either secondary or primary care/community settings. This includes doctors, dentists, midwives and nurses, vaccinators, paramedics and ambulance drivers, pharmacists, optometrists, occupational therapists, physiotherapists, radiographers and any associated support staff of independent contractors. It should include those working in public, private, third sector and non-standard healthcare settings such as hospices, and community-based mental health or addiction services. It should include Healthcare Improvement Scotland inspectors who are required to visit premises. Temporary staff, including those working in the COVID-19 vaccination programme, students, trainees and volunteers who are working with patients must also be included.
2	**Non-clinical but patient facing staff in secondary or primary care/community healthcare settings.** This includes non-clinical ancillary staff who may have social contact with patients but are not directly involved in patient care. This group includes receptionists, ward clerks, porters and cleaners.
2	**Laboratory and pathology staff** Hospital-based laboratory and mortuary staff who frequently handle SARS-CoV-2 or collect or handle potentially infected specimens, including respiratory, gastrointestinal and blood specimens should be eligible as they may also have social contact with patients. This may also include cleaners, porters, secretaries and receptionists in laboratories. Frontline funeral operatives and mortuary technicians / embalmers are both at risk of exposure and likely to spend a considerable amount of time in care homes and hospital settings where they may also expose multiple patients. However, not included here are staff working in non-hospital-based laboratory and those academic or commercial research laboratories who handle clinical specimens or potentially infected samples as they will be able

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	to use effective protective equipment in their work and should be at low risk of exposure.
2	**Social care staff directly involved in the care of their service users and others involved directly in delivering social care such that they and vulnerable patients/clients are at increased risk of exposure** This includes, for example, workers in residential care for adults and children, supported housing, and also personal assistants and social workers who have face-to-face contact in the course of their duties including child, adult, mental health officer duties and public protection. It should include Care Inspectorate staff who are required to visit care homes and other registered services. Young people age 16-18 years, who are employed in, studying or in training for health and social care work should be offered vaccination alongside their colleagues if a suitable vaccine is available.
3	**all those 75 years of age and over**
4	**all those 70 years of age and over and clinically extremely vulnerable individuals**
5	**all those 65 years of age and over**
6	**all individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality**
6	**Unpaid carers, including all adult carers and young carers aged 16 to 18**
7	**all those 60 years of age and over**
8	**all those 55 years of age and over**
9	**all those 50 years of age and over**

Eligibility and Additional Advice

The JCVI has amended its previous highly precautionary advice on Covid-19 vaccines and pregnancy or breastfeeding. Vaccination with either vaccine in pregnancy should be considered where the risk of exposure SARS-CoV2 infection is high and cannot be avoided, or where the woman has underlying conditions that place her at very high risk of serious complications of Covid-19, and the risks and benefits of vaccination should be discussed. Those who are trying to become pregnant do not need to avoid pregnancy after vaccination, and breastfeeding women may be offered vaccination with either vaccine following consideration of the woman's clinical need for immunisation against COVID-19. The UK Chief Medical Officers agree with this advice.

Advice has also changed in relation to use of the Pfizer BioNTech vaccine for those with allergies. Guidance now sets out that there are very few individuals who cannot receive the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines. The vaccine should not be given to those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to:

- a previous dose of the same COVID-19 vaccine
- any component (excipient) of the COVID-19 vaccine

The clinical requirement for 15-minute patient observation after vaccination set out for the Pfizer BioNTech vaccine is not required for the AstraZeneca vaccine.

Further guidance and a full list of eligible groups can be found in the most recent COVID-19 chapter (chapter 14a) of the Green Book available at:
https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a

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This is subject to change and updates will be made in the linked page above.

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ANNEX D CONTRACTUAL ARRANGEMENTS AND FURTHER INFORMATION

Contractual arrangements

Information on payments associated with the COVID-19 vaccines have been set out by Primary Care Directorate, Scottish Government.

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