

E: vaccinationsdelivery@gov.scot

Dear Colleagues

COVID-19 VACCINATION PROGRAMME

1. This letter sets out the arrangements for the initial stages of the Covid-19 vaccination programme. You will receive a further letter in relation to further stages, once future vaccine supply has been confirmed.
2. I would like to begin by thanking you for all your hard work so far in what is undoubtedly one of the most complex logistical and operational programmes we have faced. I know that this has been an extremely challenging time for staff across the health and social care sector.
3. We recognise that delivering this programme is more challenging than anything we have faced before but it is imperative that we do all that we can to reduce the impact of COVID-19 on those most at risk. It is therefore essential that we have effective plans in place to deliver COVID-19 vaccines to protect those most at risk, prevent ill health in the population and minimise further pressure on the NHS and social care services

Key Objectives

4. To commence the COVID-19 vaccination programme in line with JCVI prioritisation, set out in Annex B.
5. To protect those most at risk by achieving high vaccine uptake amongst the first priority groups.
6. To make best use of the limited initial doses of vaccines available, recognising the particular requirements relating to the vaccine, as set out in conditions of authorisation here:
<https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/conditions-of-authorisation-for-pfizerbiontech-covid-19-vaccine>

Phased Approach

7. We anticipate receiving around 476,000 doses of the Pfizer BioNtech vaccine in December.

**From Interim Chief Medical Officer
Dr Gregor Smith**

Date: 4 December 2020

SGHD/CMO(2020)33

AddressesFor 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
 CPHMs
 Scottish Prison Service
 Scottish Ambulance Service
 Occupational Health Leads

For information

Chairs, NHS Boards
 Infectious Disease Consultants
 Consultant Physicians
 Chief Executive, Public Health Scotland
 NHS 24

Further EnquiriesPolicy Issues

COVID Vaccination Policy Team
VaccinationsDelivery@gov.scot

Medical Issues

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Pharmaceutical and Vaccine Supply Issues

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8. Please note that in line with MHRA advice, 50 per cent of doses available in the first phase must be held back to use as second doses. A phased approach is therefore required. This initial phase will cover the groups set out in table in Annex A.
9. We anticipate then working through the further priority groups as vaccine supply allows.

Communication materials

10. The phased approach required by the limited vaccine supply means that a careful communications approach is required.

Materials for staff

11. Separate communications toolkits for health care workers and social care workers to be vaccinated will be made available to staff on Friday 4th December. These toolkits will be similar to what you receive 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.
12. Workforce education materials are available on the Turas Learn site.

Materials for care homes

13. Consent packs will be sent to care homes, including a letter, a leaflet, consent form and post-immunisation card for each resident.

Materials for the public

14. In later phases of the programme, when more vaccines are available and as individuals become eligible, they will be invited to attend for vaccination (via letter and accompanying leaflet). This will be in addition to a national, local and sectoral public information campaign.

Key contact points

15. For more information, members of the public will be asked to visit nhsinform.scot/covid19vaccine or call 0800 030 8013.
16. The MHRA is asking that suspected side effects to medicines, vaccines, or medical devices used in COVID-19 treatment are reported via the dedicated Coronavirus Yellow Card reporting site: <https://coronavirus-yellowcard.mhra.gov.uk/>

Resources

17. NHS Boards are asked to ensure immunisation teams are properly resourced to develop and deliver the COVID-19 vaccination programme, alongside the extended seasonal flu vaccination programme, noting that additional costs will be met by the Scottish Government. The established financial allocation approach we have in place will support this process and should ensure that there are no barriers or delays to delivering this programme.
18. 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

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

20. It is critically important that every effort is made to ensure high uptake, and that those eligible to receive a vaccine do so. Due to limited supply of vaccine initially, ongoing and effective management at a local level is required.

21. Thank you for your continued support in delivering the COVID-19 vaccination programme

Yours sincerely,

Gregor Smith

Gregor Smith
Interim Chief Medical Officer

ANNEX A: INITIAL 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	Vaccine to be taken to Care Homes once packing down, delivery and stability issues resolved
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	Provide assistance to take Care Home Workers to NHS Board vaccination centres and Vaccinate in Care Homes when we are able to take vaccine there
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

Please note that we are not recommending that we call over 80s who are not long stay inpatients or Care Home residents for vaccination at this stage.

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

Pfizer-BioNTech Vaccine

22. The Pfizer vaccine is the first vaccine to be approved for use in the United Kingdom and will be the primary vaccine to begin
23. The vaccine is a lipid nanoparticle-formulated mRNA vaccine. The mRNA encodes the SARS-CoV-2 receptor-binding domain of the spike protein. The mRNA in the vaccine is translated and transcribed by the body to produce this key part of the spike protein. The protein then acts as an intracellular antigen to stimulate the immune response. The mRNA in the vaccine is normally degraded within a few days and cannot incorporate into the host genome. Data from the Pfizer-BioNTech vaccine trials undertaken in over 40,000 individuals indicate high vaccine efficacy, with no serious safety concerns observed.

Vaccine Composition

24. This is a multidose vial and must be diluted before use. 1 vial (0.45 mL) contains 5 doses of 30 micrograms of BNT162b2 RNA (embedded in lipid nanoparticles).
25. COVID-19 mRNA Vaccine BNT162b2 is highly purified single-stranded, 5'-capped messenger RNA (mRNA) produced by cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2.
26. Further detail is available here:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940565/Information_for_Healthcare_Professionals_on_Pfizer_BioNTech_COVID-19_vaccine.pdf

Delivery arrangements

27. The vaccine will be delivered to authorised holding sites within Boards that are capable of handling medicines at ultra-low temperatures. 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 COVID-19 mRNA Vaccine BNT162b2 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.



ANNEX C JCVI PRIORITISATION and VACCINE ELIGIBILITY

28. The table below sets JCVI advice for priority groups which subsequently will guide how we deliver the vaccine

Priority Group	Risk Group
1	Residents in a care home for older adults and their carers
2	All those 80 years of age and over Frontline health and social care workers
3	All those 75 years of age and over
4	All those 70 years of age and over 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
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
*	Clinically extremely vulnerable individuals are here . This advice on vaccination does not include pregnant women and those under the age of 16 years

29. Full details of the JCVI's 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>

30. It should be noted that the vaccine is not recommended for those who are pregnant, those who may be pregnant or those who are breastfeeding. Pregnancy should also be avoided for at least two months after the second dose.

31. 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>

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

ANNEX D CONTRACTUAL ARRANGEMENTS AND FURTHER INFORMATION

Contractual arrangements

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

