Chief Medical Officer

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The Scottish Government
Riaghaltas na h-Alba

Dear Colleague

MONKEYPOX (MPX) PRE AND POST EXPOSURE VACCINATION

1. This letter provides information on the current monkeypox (MPX) outbreak, and the actions that are being put in place to ensure that those groups considered to be a priority are offered protection through vaccination.

2. Advice on the management of suspected or confirmed cases has been set out in a separate CMO letter, published on 21 May 2022, Monkeypox (MPX) cases in the UK – investigation and assessment of individuals suspected to have MPX and management of confirmed cases of MPX (scot.nhs.uk).

3. Individuals who are considered to be in one of the priority groups for vaccination against MPX should now be offered Modified Vaccinia Ankara - Bavarian Nordic (MVA-BN) vaccine on a pre-exposure basis.
4. Vaccines are available to order and Health Boards should offer to priority groups as soon as possible.

Background

5. MPX is a rare viral infection that does not spread easily between people. It is usually a self-limiting illness, with most people making a complete recovery within a few weeks. However, severe illness can occur in some individuals. The infection can be spread when someone is in close contact with an infected person, however, there is a very low risk of transmission to the general population.

6. Within the current outbreak, those who are considered at high risk of MPX may have had sexual contact or other very close contact with infected individuals. (As outlined in annex A). Additionally, some healthcare workers (HCWs) within particular clinical settings are considered to be at risk of contracting the disease.

Joint Committee on Vaccination and Immunisation considerations

From the Chief Medical Officer Chief Nursing Officer Chief Pharmaceutical Officer
Professor Sir Gregor Smith
Professor Alex McMahon
Professor Alison Strath

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Addresses

For action
Chief Executives;
NHS Boards;
Medical Directors;
Directors of Public Health;
Nurse Directors;
NHS Board Executive Leads for Sexual Health;
NHS Boards Primary Care Leads;
NHS Boards Infectious Disease Consultants;
NHS Board Immunisation Coordinators;
NHS Board Medical Directors;
Nurse Directors;
NHS Boards Directors of Public Health;
Infectious Disease Consultants;
CPHMs Consultant Physicians;
General Practitioners Practice;
Nurses Consultants in Public Health;
Accident and Emergency;
Departments Virology Laboratories;
Travel Clinics;
Directors of Pharmacy;
Chief Executive NHS 24 Sexual;
Health Services;
SAS Occupational Health;
GP OOH

For information
Public Health Scotland;
Directors of Dentistry;
Optometrists;
General Practitioners;
Practice Nurses;
Primary Care Leads;
NHS Boards;
NHS Board Chief Executives;
Directors of Pharmacy;
Consultant Physicians;
Public Health Scotland;

7. The Joint Committee on Vaccination and Immunisation (JCVI) convened an extraordinary meeting on 25 May to discuss the vaccination strategy for the ongoing MPX outbreak. The current concern relates to ongoing transmission, mainly in those who are GBMSM (gay, bisexual and other men who have sex with men), with the majority of cases to date located in London. The JCVI did not publish a statement on their deliberations, but have provided advice to UKHSA, who have incorporate this into guidance.

Recommended Vaccine and Use cases

8. The MVA-BN Smallpox vaccine is the recommended vaccine for pre and post-exposure prophylaxis against MPX in the UK. A full course of MVA-BN vaccine is comprised of two doses given at least 28 days apart.

9. MVA-BN is being used off-label in the UK for MPX. UKHSA guidance advises that if vaccination is to be used for post-exposure prophylaxis, the vaccine is most effective if given within four days of exposure to prevent onset of disease but can be given up to 14 days post-exposure to reduce severity of disease, if required.

10. Units caring for suspected MPX cases must minimise the number of staff attending to such patients face to face and should consider alternative patient and staff pathways/triage.

11. Further information is included in the Annex set out below.

Action

12. Health Boards are requested to action this guidance and ensure that their vaccination teams are made aware ofthe latest advice.

Chief Executive;
NHS Health Scotland;
NHS 24;
Scottish General Practitioners' Committee

Further Enquiries to:

Policy Issues

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Yours sincerely

Professor Sir Gregor Smith	*Professor Alex McMahon*	*Professor Alison Strath*
Chief Medical Officer	**Chief Nursing Officer**	**Chief Pharmaceutical Officer**

Annex A

MPX Vaccination Programme

Background and Principles

1. The transmission of MPX requires sustained close contact. At this stage, in Scotland, no cases of MPX have been admitted to hospital. Within this current outbreak, most suspected cases of MPX are assessed in sexual health clinics/settings and then managed at home. Any hospital admissions for suspected MPX would be referred to a regional infectious disease unit or other designated unit where appropriate PPE will be worn.

2. The current outbreak in the UK has thus far led to no HCWs having contracted MPX as a result of their work. HCW's attending to a suspected case of MPX should wear PPE as per the current guidance, which can be found here.

3. Patients requiring hospital admission may pose more of a risk, due to potential higher risk of shedding and the duration of contact or hospital admission. HCW's changing bed linen and staff who are regularly undertaking environmental decontamination around cases of MPX are advised to use PPE.

4. Assessment for post exposure vaccination (within 4 days) is recommended for HCWs who have had contact with a suspected or confirmed case of MPX and where PPE has not been appropriately worn. This includes staff who have assessed patients with MPX in non-designated settings such as emergency or primary care. Staff should be made aware of the availability of post exposure vaccination and the need to refer very promptly post potential exposure.

Pre-exposure vaccination

5. Vaccination should be offered as soon as feasible to those considered to be at high risk in the GBMSM community.

6. Individuals at highest risk may be identified amongst those who attend sexual health services, using markers of high-risk behaviour similar to those used to assess eligibility for HIV pre-exposure prophylaxis (PrEP), but applied regardless of HIV status. These risk criteria would include:

- Prescribed PrEP or meets the eligibility criteria for PrEP in terms of sexual history
- A recent history of multiple partners
- Participating in group sex
- Aattending sex on premises venues
- Planning to travel with sexual contact with new partners at destination
- A proxy marker such as recent bacterial STI (in the past year), including early syphilis.

7. There may be other groups or risk behaviours at clinician discretion. Staff at any sex on premises venues should also be considered for pre-exposure vaccination; and should be advised to follow guidance on wearing PPE, particularly when cleaning.

8. Wider vaccination in low risk GBMSM individuals or the general population is not advised at this time, in view of the current epidemiology and vaccine supply.

9. Further details can be found in the Green Book, chapter 29 - Smallpox and monkeypox: the green book, chapter 29 - GOV.UK (www.gov.uk)

Occupational vaccination

10. Pre-exposure vaccination should also be offered to staff considered to be at the highest risk of infection within Regional Infectious Diseases Units, Sexual Health or Genitourinary Medicine (GUM) clinics, such as those assessing and investigating MPX cases.

11. Healthcare staff (including those in other healthcare settings) should be able to avoid inadvertent exposure by ensuring suspected MPX cases are assessed by designated staff, and by wearing appropriate personal protective equipment.

Post–exposure vaccination

12. It is recommended that post-exposure vaccination of high-risk community or occupational contacts is offered ideally within 4 days of exposure, although may be offered up to 14 days in those at ongoing risk, or who are at higher risk of the complications of MPX.

Those at higher risk of complications include:

- Children under the age of 10-11 years
- People who are pregnant
- Individuals with immunosuppression (as defined in the Green Book) Monkeypox (MPX) cases in the UK – investigation and assessment of individuals suspected to have MPX and management of confirmed cases of MPX (scot.nhs.uk)

13. This advice is given within the context of the current epidemiological situation in the UK where disease is typically mild and transmission occurring within the GBMSM population. It is also given with the consideration that vaccine supply is limited.

14. The UKHSA advice and guidance will be kept under review as the outbreak develops, with JCVI consulted where appropriate. UKHSA will also evaluate the impact of vaccination on the outbreak.

15. Public Health Scotland is currently involved in supporting Health Boards with risk assessment of cases and contacts.

Vaccine

16. The MVA-BN vaccine is the current recommended vaccine for pre and post-exposure prophylaxis against MPX in the UK.

Vaccine ordering and supply

17. A UK stockpile of MVA-BN vaccine has been procured by the UKHSA; the volume of stock currently available is limited.

18. An initial allocation of stock has been communicated to Health Boards and can be ordered via Immform; Health Boards should begin offering the vaccine to priority groups as soon as feasible.

19. It is recommended that Health Boards hold a minimum reserve of **5 doses** locally to enable a quick response to requests for post-exposure prophylaxis including over weekends.

Vaccine Usage and Administration

20. Pre-exposure vaccination of individuals previously not vaccinated against smallpox: administer a course of two doses, with at least a 28-day interval between doses, for instance:

    - first dose of MVA-BN vaccine 0.5ml, then
    - second dose of MVA-BN vaccine 0.5ml at least 28 days after the first dose.

21. Post-exposure of individuals of any age: administer a single 0.5ml dose of MVA-BN vaccine.

22. First doses should be prioritised during this outbreak, with the offer of a second dose for those who continue to be at an increased risk of exposure.

23. The vaccine should be given by deep subcutaneous injection.

24. For current recommendations on MVA BN vaccine use and administration, vaccinators should refer to the Green Book Smallpox and Monkeypox: the green book, chapter 29 - GOV.UK (www.gov.uk) Due to an increased risk of site associated reactions, individuals with atopic dermatitis should have a risk assessment before being offered vaccination.

Vaccine Storage

25. MVA-BN is supplied frozen in packs of 20 vials. Where possible, the vaccine should be stored within Health Boards at -20ºC to maximise shelf life. Frozen vials should be transferred to 2°C to 8°C to thaw or may be thawed for 15 minutes at room temperature for immediate use. After thawing, vaccine can be stored for up to 8 weeks at 2°C to 8°C. Store in the original package in order to protect from light.

Vaccine Stock Management

26. Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage, including the use of appropriate cool boxes/bags for transporting the vaccine. Local protocols should be put in place to keep vaccine wastage to a minimum. Even small percentage reductions in vaccine wastage have a major impact on the financing of vaccine supplies and the protection of individuals.

Vaccine Prescribing

27. MVA-BN vaccine has been authorised by the Medicines and Healthcare products Regulatory Agency for use against smallpox. As MVA-BN vaccine does not have a marketing authorisation in the UK for protection against MPX, use for this indication is considered 'off label'.

28. Off label use of medicines, including vaccines can be undertaken on the basis of additional evidence or expert opinion. In this instance, there is no UK licensed vaccine authorised specifically for use against MPX however the US FDA approval of MVA-BN for management of MPX indicates there is sufficient rationale for using MVA-BN for MPX.

29. Current available stock has been imported from Europe and is considered unlicensed; licensed stock may become available in the future. Due to the unlicensed status of current UK stock, a prescription or Patient Specific Direction is required for administration of MVA-BN. This may change in the future if licensed stock becomes available.

Workforce Education resources for Healthcare Practitioners

30. NHS Education for Scotland, in partnership with Public Health Scotland, has produced educational resources for healthcare practitioners. These resources are available at Vaccination Against Monkeypox Using MVA-BN (Imvanex®) Vaccine | Turas | Learn (nhs.scot)

PPE

31. PPE should be used in-line with MPX IPC guidance found here https://www.nipcm.hps.scot.nhs.uk/media/1876/2022-06-06-arhai-mpx-ipc-guidance-v11.pdf . Hand hygiene should be carried out prior to, and following vaccination and use of FRSM (Fluid Resistant Surgical Mask) in-line with current COVID19 guidance should be followed.

32. If PPE fails during use, then post exposure prophylaxis should be considered.

Communications Activity

33. Information to support informed consent is available as a hard copy leaflet in English and on NHS inform at: Vaccination to help protect against monkeypox: Important information for pre and post exporsure to monkeypox Public Health Scotland is happy to consider requests for other languages or formats. Please email phs.otherformats@phs.scot to request other languages or formats.

Immunisation against Infectious Disease (The Green Book)

34. The Smallpox and Monkeypox chapter (chapter 29) within Immunisation against Infectious Disease (The Green Book) can be found at: Smallpox and monkeypox: the green book, chapter 29 - GOV.UK (www.gov.uk)

Consent

35. Information on consent for vaccination can be found in chapter two of the Green Book available at: https://www.gov.uk/government/publications/consent-the-green-book-chapter-2

Reporting of adverse reactions

36. The most common Adverse Reactions (ADRs) observed are injection-site reactions. These include pain, localised itching, redness and swelling at the injection site. Other reactions commonly reported are headache, aching muscles, tiredness and feeling sick. These adverse reactions are usually mild or moderate in intensity.

37. For a detailed list of ADRs associated with MVA-BN vaccine please refer to the manufacturer's product information/SPC or the Patient Information Leaflet (PIL) supplied with each vaccine. Suspected adverse reactions (ADRs) to vaccines should be reported via the Yellow Card Scheme available at: https://yellowcard.mhra.gov.uk/.

38. Chapter 9 of the Green Book gives detailed guidance on which ADRs to report and how to do so. Additionally, Chapter 8 of the Green Book provides detailed advice on managing ADRs following vaccination.

39. Any reported adverse incidents, errors or events during or post vaccination must follow pre-determined procedures. In addition, teams must keep a local log of reports and discuss such events with the local Immunisation Co-ordinator.

Data collection

40. Health Boards should continue to record vaccine data manually as agreed with PHS. Ongoing discussions are taking place to agree on the most appropriate recording mechanism for MPX vaccination. Scottish Government (SG) teams and PHS are liaising with our UK counterparts to determine their approach.

41. SG and PHS are working on a Rapid Options Appraisal to determine the most effective method of recording vaccinations. Further detail will be communicated to Health Boards and vaccination services.

Funding arrangements

42. The Scottish Government will fund the procurement and the supply of the MPX vaccine to Health Boards.