UK Health Security Agency

Publications gateway number: GOV-12920

Smallpox vaccine Patient Group Direction (PGD)

This PGD is for the administration of the smallpox vaccine, non-replicating, live modified vaccinia virus Ankara - Bavarian Nordic (MVA-BN), to individuals identified for immunisation in response to monkeypox in the UK. This PGD allows only the use of US licensed Batch FDP00012 of Jynneos® vaccine.

This PGD is for the administration of smallpox vaccine by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	Smallpox vaccine PGD
Version no:	v1.00
Valid from:	2 August 2022
Review date:	2 January 2023
Expiry date:	1 August 2023

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Current versions of UKHSA PGD templates for authorisation can be found from: Immunisation patient group direction (PGD) templates

Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk.

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: The Screening and Immunisation Team, NHS England – Midlands, responsible for your area:

[1] This includes any relevant amendments to legislation.

East (Derbyshire & Nottinghamshire and Leicester, Leicestershire, Rutland, Lincolnshire & Northamptonshire) england.emids-imms@nhs.net

West (Shropshire, Staffordshire, Birmingham, Coventry, Dudley, Herefordshire, Sandwell, Solihull, Walsall, Warwickshire, Wolverhampton & Worcestershire)
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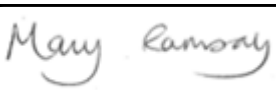
Change history

Version number	Change details	Date
V01.00	New smallpox vaccine PGD template to: • respond to the outbreak of monkeypox in accordance with the national guidelines; Recommendations for the use of pre and post exposure vaccination during a monkeypox incident and updated Green Book Chapter 29, 21 June 2022 • include information regarding the use of US licensed Jynneos® as there are no stocks of the UK licensed MVA-BN vaccine Imvanex® currently available. Jynneos® is being issued in view of the urgency of the need to manage the monkeypox outbreak. MHRA has granted Batch-Specific Variation to permit the importation of batch FDP00012 of the Jynneos brand of MVA-BN vaccine, which is licensed in the US by the Food and Drug Administration (FDA). Both vaccines are developed by Bavarian Nordic. The conditions of regulatory approval by the MHRA vary slightly from those of the FDA for the US market. At present, there is unlicensed Imvanex® vaccine in use on PSD basis. • include under characteristics of staff additional requirements the condition to be familiar with the Direct Health Professional Communication from manufacturer for Jynneos® vaccine	2 August 2022

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		2 August 2022
Doctor	Mary Ramsay Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		2 August 2022
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		2 August 2022

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been approved by the UKHSA Medicines Governance Group and ratified by the UKHSA Clinical Quality and Oversight Board.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Gayatri Amrithalingam	Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHS England (NHSE)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Shamez Ladhani	Paediatric Infectious Disease Consultant, UKHSA
Jacqueline Lamberty	Lead Pharmacist, Medicines Governance, UKHSA
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHSE (South West)
Gill Marsh	Principal Screening and Immunisation Manager, NHSE (North West)
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Tushar Shah	Lead Pharmacy Advisor, NHSE (London)

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England -Midlands authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Primary care services and/or all organisations commissioned or contracted by NHS England – Midlands to provide immunisation services in: Derbyshire, Nottinghamshire, Leicestershire, Lincolnshire, Northamptonshire, Shropshire, Staffordshire, Birmingham, Coventry, Dudley, Herefordshire, Sandwell, Solihull, Walsall, Warwickshire, Wolverhampton and Worcestershire
Limitations to authorisation

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Director of Primary Care and Public Health Commissioning – NHS England – Midlands	Trish Thompson		17.08.2022

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to The Screening and Immunisation Team, NHS England – Midlands, responsible for your area:

East (Derbyshire & Nottinghamshire and Leicester, Leicestershire, Rutland, Lincolnshire & Northamptonshire) england.emids-imms@nhs.net

West (Shropshire, Staffordshire, Birmingham, Coventry, Dudley, Herefordshire, Sandwell, Solihull, Walsall, Warwickshire, Wolverhampton & Worcestershire)
england.wmid-imms@nhs.net

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the 'Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the cold chain • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources • must have read and be familiar with the contents of the Direct Healthcare Professional Communication from Bavarian Nordic on the differences between Imnavex® brand (licensed in GB/UK) and Jynneos® brand (licensed in US) of Live Modified Vaccinia Virus Ankara • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from the UKHSA and/or NHSE and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the pre and post exposure immunisation of individuals against monkeypox virus, in accordance with national guidance; Recommendations for the use of pre and post exposure vaccination during a monkeypox incident and the recommendations given in Chapter 29 Immunisation Against Infectious Disease: The 'Green Book' and the monkeypox vaccination programme
Criteria for inclusion	Individuals who: • are recommended immunisation as a contact of a case of monkeypox • are at risk of monkeypox exposure in accordance with national guidance; Recommendations for the use of pre and post exposure vaccination during a monkeypox incident and the recommendations given in Chapter 29.
Criteria for exclusion[2]	Individuals for whom valid consent has not been obtained (for further information on consent see Chapter 2 of 'The Green Book'). Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of MVA-BN vaccine or to any component of the vaccine (including trace residues from the manufacturing process such as chicken protein, benzonase, gentamicin and ciprofloxacin) • are acutely unwell. Immunisation may be postponed until they have fully recovered. Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine All healthcare workers (HCWs) are excluded from this PGD. Under the NHSE monkeypox specification, all HCWs are excluded from receiving monkeypox vaccine as part of the NHS service. HCWs will therefore need to be vaccinated using a PSD or Written Instruction in accordance with the NHSE guidance for the delivery of vaccination for monkeypox.
Cautions including any relevant action to be taken (Continued over page)	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council. Individuals with atopic dermatitis develop more local and general symptoms after vaccination with MVA-BN vaccine. For further information see Green Book Chapter 29. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered. Seek medical advice as appropriate (see Chapter 29). **Pregnancy** Although MVA-BN has not formally been evaluated in pregnancy, animal studies (three studies in female rats) identified no vaccine related fetal

[2] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Cautions including any relevant action to be taken (continued)	malformations. Use of MVA-BN in pregnant women is limited to less than 300 pregnancies without leading to any adverse events on pregnancy. As it is a non-replicating vaccine, there is no theoretical reason for concerns in pregnancy and the adverse events profile would be expected to be similar to that in non-pregnant vaccinees. Whilst it is not recommended for use in pregnancy, any theoretical risk needs to be weighed against the maternal risks of exposure to monkeypox in late pregnancy (such as a risk of more severe disease from viral infections in the third trimester) and any consequent fetal risks from maternal infection in early pregnancy. **Breast-feeding** It is not known whether MVA-BN is excreted in human milk, but this is unlikely as the vaccine virus does not replicate effectively in humans. Women who are breast feeding and have a significant exposure to monkeypox should therefore be offered vaccination, after discussion about the risks of monkeypox to themselves and to the breast-fed child. **Immunosuppression including HIV infection** MVA-BN is a replication defective virus and should pose no risk to those who are immunosuppressed. The safety and immunogenicity of MVA-BN in persons living with HIV infection (with CD4 cell counts above 100 cells/mm3) has been demonstrated (Greenberg et al, 2013). However, the immune response to the vaccine could be reduced in severely immunosuppressed individuals, so additional precautions may be needed. Vaccination should generally proceed in accordance with recommendations, as these individuals are also at significant risk of the complications of monkeypox (see Green Book Chapter 29 and Recommendations for the use of pre and post exposure vaccination during a monkeypox incident. **Current or previous monkeypox infection** If an individual is acutely unwell, including those with symptoms or signs of possible monkeypox infection, immunisation should be postponed until they have fully recovered. This is to both reduce risks of exposing others and to avoid wrongly attributing any signs or symptoms to the adverse effects of the vaccine. Whether prior monkeypox infection protects against future infection is currently unknown but based on analogy from smallpox infection and from live smallpox vaccine, it seems likely that re-infection will be unusual, particularly in the short term. Although previous monkeypox infection is not a contra-indication to vaccination, in a situation of constrained vaccine supply, it is therefore recommended that vaccination of confirmed cases is deferred. If supply allows, vaccination may be considered for those at on-going risk once fully recovered.
Action to be taken if the patient is excluded (Continued over page)	If a confirmed anaphylactic reaction has been experienced after a previous dose of MVA-BN or any of its components, specialist advice should be sought. If the individual is a potential contact of monkeypox and is suffering from acute severe febrile illness, they should be referred for a clinical assessment to be appropriately advised. Other individuals with febrile illness who are not at immediate risk of exposure, and who are suffering acute severe febrile illness may postpone immunisation until they have recovered. Immunisers should advise when the individual can be vaccinated, and ensure another appointment is arranged at the earliest opportunity. National guidance, Recommendations for the use of pre and post exposure vaccination during a monkeypox incident provides principles for

Action to be taken if the patient is excluded (continued)	risk assessment and follow up of contacts of confirmed monkeypox cases. It is intended to support risk assessment and categorisation of contacts to ensure they are offered appropriate isolation advice and vaccination. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the individual's clinician as appropriate.
Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained for each administration. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and the decision reached. Inform or refer to the individual's clinician as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength and formulation of drug	MVA-BN suspension for subcutaneous injection (SC) (See off-label section below for intramuscular (IM) use). Jynneos® packaging states: Each 0.5ml dose contains 0.5 x 10^8 to 3.95 x 10^8 infectious units of non-replicating, live MVA-BN. Note: This PGD allows only the use of US licensed Batch FDP00012 of Jynneos® vaccine.
Legal category	Prescription only medicine (POM) See batch specific information above under name, strength and formulation section.
Black triangle▼	Yes
Off-label use	Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. MVA-BN is not indicated for active immunisation against monkeypox in the UK. However, the vaccination is approved for the prevention of monkeypox in the US and has been used in the UK in response to monkeypox incidents. MVA-BN may be administered under this PGD for active immunisation against monkeypox in accordance with Green Book Chapter 29 and Recommendations for the use of pre and post exposure vaccination during a monkeypox incident. Although the MVA-BN vaccine is not indicated for children, several paediatric studies of other vaccines using MVA as a vector (often at a considerably higher dose than used in MVA-BN) have been undertaken with a reassuring side effect profile. The vaccine should therefore be offered to children considered to be at risk, as children seem to have a more severe presentation of monkeypox. Jynneos® is only licensed for subcutaneous use, however, the Green Book Chapter 29 allows the vaccine to be used subcutaneously or intramuscularly. No data for co-administration of MVA-BN vaccine with other vaccines exist and concomitant administration of MVA-BN with other vaccines is not recommended. In the absence of such data first principles would suggest that interference between inactivated (non-replicating) vaccines with different antigenic content is likely to be limited (see Chapter 11) based on experience with other vaccines. Any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult (see Chapter 29). Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.

Route and method of administration	The vaccine can be given subcutaneously or intramuscularly. A dose of 0.5 ml is withdrawn into a syringe for injection and administered by the deep subcutaneous route (see Chapter 4) or intramuscular route. The preferred sites for IM and SC immunisation are the anterolateral aspect of the thigh or the deltoid area of the upper arm. The anterolateral aspect of the thigh is the preferred site for infants under one year old because it provides a large muscle mass into which vaccines can be safely injected. Allow the vaccine to thaw. The vaccine should be allowed to reach room temperature before use. Frozen vials should be transferred to 2°C to 8°C to thaw or may be thawed for 15 minutes at room temperatures for immediate use (Chapter 29). Vaccines previously stored at -20°C +/-5°C, can be stored at 2°C–8°C in the dark for up to 8 weeks prior to use. Do not re-freeze a vial once it has been thawed. The vaccine's normal appearance is a light yellow to pale white milky suspension. The suspension should be visually inspected for particulate matter and discoloration before use. In the event of any damage to the vial, foreign particulate matter and/or variation of physical aspect being observed, the vaccine should be discarded. Swirl the vial gently before use for at least 30 seconds. Withdraw a dose of 0.5 ml into a sterile syringe for injection. The vaccine must not be mixed with other medicinal products. When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records Green Book Chapter 4).
Dose and frequency of administration (Continued over page)	**Pre-exposure vaccination of individuals previously not vaccinated against smallpox** Single 0.5ml dose of MVA-BN per administration Administer a course of two doses with at least a 28-day interval between doses, for instance: • first dose of MVA-BN 0.5ml, then • second dose of MVA-BN 0.5ml at least 28 days after the first dose. In the event of an incident, it is highly unlikely that there will be sufficient time to offer pre-exposure vaccination with two doses at those at risk of exposure. In this case, a single dose of vaccine should be offered immediately. Completion of the primary course with a second dose at least 28 days later should be considered on assessment of ongoing risk of exposure. Where the second dose of MVA-BN is given beyond 28 days, the first dose should not be repeated (see Green Book Chapter 29). Vaccination should be offered as soon as feasible to those gay, bisexual and other men who have sex with men (GBMSM) at highest risk of exposure. The initial priority is to deliver first doses to as many GBMSM in the highest risk group as possible. Subject to the evolving epidemiology, a second dose may be advised around 2-3 months later to provide longer lasting protection as per JCVI guidance (see Green Book Chapter 29).

Dose and frequency of administration (continued)	**Pre-exposure vaccination of individuals previously vaccinated against smallpox** Administer one 0.5 ml dose of MVA-BN. Individuals who have previously been vaccinated against smallpox with a live smallpox vaccine should receive a single dose of 0.5 ml. **Post-exposure vaccination** Administer one 0.5 ml dose of MVA-BN. To maximise the chance of preventing infection, MVA-BN should preferably be administered within 4 days from the date of exposure to monkeypox. The objectives of immunisation are to provide protection against infection and to modify disease severity in individuals of any age with recent exposure to monkeypox. Post-exposure vaccination of high risk community contacts is offered, ideally within 4 days of exposure, although may be offered up to 14 days in those at on-going risk (for example during an outbreak) or those who are at higher risk of the complications of monkeypox - this includes children below the age of five years, pregnant women and individuals with immunosuppression. (Green Book Chapter 29). Individuals who have previously received a two dose course of MVA-BN, with the second dose given in the past two years, do not need a further dose of vaccine after exposure. The exception is those who are immunosuppressed, who may have made a lower or less durable immune response, for whom an additional dose can be considered (Green Book Chapter 29). **Booster vaccination** Administer one 0.5 ml dose of MVA-BN. Immunocompetent individuals who have previously been vaccinated against smallpox should receive a single dose MVA-BN 0.5 ml, no less than two years after the primary course if they are considered to be at on-going risk of exposure or in the event of an exposure incident (Green Book Chapter 29). **Previous incomplete vaccination** If the MVA-BN course is interrupted or delayed, it should be resumed but the first dose does not need to be repeated.
Duration of treatment	See Dose and Frequency section above
Quantity to be supplied and administered	Single 0.5ml dose per administration.
Supplies (Continued over page)	Currently, there are no stocks of the UK licensed MVA-BN vaccine Imvanex® available hence US licensed Jynneos® is being issued in view of the urgency of the need to manage the monkeypox outbreak. Batch FDP00012 has been granted Batch -Specific Variation by the MHRA to allow importation of the Food and Drug Administration (FDA)-licensed Jynneos® brand of the MVA-BN vaccine in the US. Both vaccines are developed by Bavarian Nordic. The conditions of regulatory approval by the MHRA vary slightly from those of the FDA for the US market. Imvanex® branded supplies in England in spring/summer 2022 are product imported from the EU in response to monkeypox cases and do not have licensed medicine status in England. These batches are considered unlicensed in England and cannot be supplied or administered under this PGD and are given on PSD basis. Centrally purchased vaccines for a monkeypox incident response are available from the UKHSA for providers to access in accordance with the

Supplies (continued)	incident response recommendations. Contact the UKHSA vaccine supply team (see Chapter 29). Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 'Green Book' Chapter 3).
Storage	Keep frozen at -20°C (± 5°C). After thawing at room temperature, the vaccine should be used immediately. From the time of thawing and transfer from –20°C (± 5°C) storage to the refrigerator at 2-8°, the vaccine can be stored at 2°C to 8°C in the dark for up to 8 weeks prior to use. Store in the original package to protect from light. Do not re-freeze a vial once it has been thawed. Do not use the vaccine after the expiry date shown on the vial label. In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal, refer to Vaccine Incident Guidance.
Disposal	MVA-BN contains genetically modified organisms (GMOs). Sharps waste and empty vials should be placed into yellow lidded waste bins and sent for incineration; there is no need for specific designation as GMO waste. An appropriate virucidal disinfectant should be available for managing spills in all settings where vaccination is administered. Potentially contaminated gloves and aprons can be disposed in yellow/black striped bags for offensive waste (see Chapter 29). Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. The concomitant administration of MVA-BN with any immunoglobulin including Vaccinia Immune Globulin (VIG) has not been studied and should be avoided.
Identification and management of adverse reactions (Continued over page)	The most common adverse injection site reactions include pain, redness, swelling, induration, itching and common systemic reactions include chills, fever (temperature ≥ 38°C), muscle pain, fatigue, headache and nausea. Typical for vaccines, reactions which were mild to moderate in intensity resolved without intervention within six days following vaccination. Individuals with atopic dermatitis are known to have developed more site-associated reactions and generalized symptoms following MVA-BN vaccination. Individuals in this group therefore need to have a risk assessment before being offered vaccination. The assessment should consider the risk of exposure, the risk of side effects from vaccination and the potential use of alternative preventive interventions (Green Book Chapter 29). The vaccine may trigger local rashes or more widespread eruptions. Events of rash after vaccination (related cases observed in 0.4% of subjects) tend to occur within the first days after vaccination, are mild to moderate in intensity and usually resolve without sequelae.

Identification and management of adverse reactions (continued)	Hypersensitivity reactions and anaphylaxis can occur after vaccination but are very rare. A detailed list of adverse reactions is available in the Imvanex® SPC. The Direct Healthcare Professional Communication (DHPC) 8 July 2022 from Bavarian Nordic, the manufacturer, signposts to the Imvanex® information on the MHRA website.
Reporting procedure of adverse reactions	Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's clinician should be informed.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet provided with the vaccine. • UKHSA Protecting you from monkeypox; information on the smallpox vaccination • Patient Information Leaflet (PIL) DHPC from Bavarian Nordic advises healthcare professionals to provide Jynneos® package insert included in the outer packaging to individuals receiving a vaccine • Monkeypox vaccination resources • Monkeypox: waiting for your vaccination Monkeypox vaccination resources - GOV.UK (www.gov.uk) • Monkeypox vaccination record card Monkeypox vaccination resources - GOV.UK (www.gov.uk) • Provide the relevant leaflets as recommended in the national guidance Recommendations for the use of pre and post exposure vaccination during a monkeypox incident
Patient advice and follow up treatment	Inform the individual of possible side effects and their management. The individual should be advised to seek medical advice in the event of an adverse reaction. Advise the individual when the next dose is due. If administration is postponed advise the individual when to return for vaccination. Provide the individual with further advice and leaflets as recommended in the national guidance Recommendations for the use of pre and post exposure vaccination during a monkeypox incident.
Special considerations and additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.
Records (Continued over page)	Record: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2005 • name of individual, address and date of birth • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • it is a black triangle product

Records (continued)	• anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or a password-controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous. It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. A monkeypox vaccination card should be completed and given to the individual. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**Smallpox vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 29, last updated 3 August 2022. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for Imvanex® January 2021 MHRA - 18655214367080357 51_spc-doc.doc • Patient Information Leaflet for Imvanex® January 2021 MHRA - IMVANEX-H-002596-IA-G_PI_en_Clean(2) • UKHSA-Protecting you from Monkeypox; information on smallpox vaccination Monkeypox vaccination resources - GOV.UK (www.gov.uk) • Recommendations for the use of pre and post exposure vaccination during a monkeypox incident. 17 June 2022 Monkeypox vaccination recommendations - GOV.UK (www.gov.uk) • Monkeypox: waiting for your vaccination Monkeypox vaccination resources - GOV.UK (www.gov.uk) • Monkeypox vaccination record card Monkeypox vaccination resources - GOV.UK (www.gov.uk) • Monkeypox: guidance-information and advice for healthcare professionals and general public Monkeypox: guidance - GOV.UK (www.gov.uk) • Direct Healthcare Professional Communication (DHPC): a copy of the communication from the manufacturer will accompany the vaccine and also be available on ImmForm **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

Smallpox vaccine PGD v1.00 Valid from: 2 August 2022 Expiry: 1 August 2023

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above named healthcare professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.