



**Revision History:**

<b>PGD that has been superseded</b>	New PGD	
<b>Date of change</b>	<b>Summary of Changes</b>	<b>Section heading</b>
September 2024	New PGD adapted from the PHS Administration of rabies vaccine for travel indications for the use of regular bat handlers	

**NoS Identifier:** NoS/PGD/Rabies/1596  
**Keyword(s):** Patient Group Direction PGD pre exposure prophylactic rabies vaccine volunteer bat handlers

**Policy Statement:** It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

**Review date:** The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

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                           Amended and re-  
                           authorised:

## Organisational Authorisations

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

PGD Developed/Reviewed by;

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**Approved for use within NoS Boards by;**

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		12/03/2025

**Authorised and executively signed for use within NoS Boards by;**

NHS Grampian Chief Executive	Signature	Date Signed
Adam Coldwells – Interim Chief Executive		17/03/2025

**Management and Monitoring of Patient Group Direction**

**PGD Consultative Group**

The consultative group is legally required to include a medical practitioner, a pharmacist and best practice to have a representative of the professional group who will provide care under the direction.

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**Title:**

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## 1. Clinical Situation

### 1.1. Indication

Pre-exposure and reinforcing immunisations of individuals considered to be at risk of exposure to the rabies virus. [Rabies pre- and post-exposure patient pathways](#)

### 1.2. Inclusion criteria

- Volunteer bat handlers that regularly handles bats where no formal employer can be identified.
- Valid consent has been given to receive the vaccine.

### 1.3. Exclusion criteria

Individuals who:

- require vaccination for travel purposes
- have had a confirmed anaphylactic reaction to a previous dose of any rabies containing vaccine or to any components of the vaccine e.g. ovalbumin, (refer to relevant SmPC)
- have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free
- are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
- require post exposure treatment. Seek specialist infectious disease advice.

Rabipur® contains residues of chicken proteins (e.g. ovalbumin) so an alternative rabies vaccine may be considered for pre-exposure immunisation in those with severe egg allergy.

### 1.4. Cautions/need for further advice/ circumstances when further advice should be sought from a doctor

The Green Book advises that there are very few individuals who cannot receive rabies-containing vaccines. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist or from the local immunisation or health protection team.

Individuals with immunosuppression can be given rabies-containing vaccines although these individuals may not make a full antibody response.

The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.

## Co-administration with other vaccines

Rabies vaccine can be given at the same time as other vaccines. 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.

## Syncope

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.

## Pregnancy and breastfeeding

Pregnant women and breast-feeding mothers should be given pre-exposure prophylaxis if the risk of exposure to rabies is high following a risk assessment by a health professional and rapid access to post-exposure treatment would be limited.

## 1.5. Action if excluded

Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.

Document the reason for exclusion and any action taken in accordance with local procedures.

Discuss other preventative measures that may be implemented (i.e. avoid contact with animals).

Advise of the need for immediate post-exposure first aid and seeking medical advice for post exposure treatment.

Inform or refer to the clinician in charge.

In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.

## 1.6. Action if patient declines

Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease.

Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.

Discuss other preventative measures that may be implemented (i.e. avoid contact with animals).

Advise of the need for immediate post-exposure first aid and seeking medical advice for post exposure treatment.

Document advice given and decision reached.

Inform or refer to the clinician in charge.

## 2. Description of Treatment

### 2.1. Name of medicine/form/strength

Rabipur® powder and solvent for solution for injection in pre-filled syringe.

Verorab® powder and solvent for suspension for injection

### 2.2. Route of administration

Rabies-containing vaccines should be administered by intramuscular (IM) injection preferably into the deltoid area of the upper arm. Where administration into the deltoid is not possible the anterolateral thigh can be considered. However, for individuals with a bleeding disorder, vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

### 2.3. Dosage

Rabipur®: 1ml

Verorab®: 0.5ml

## 2.4. Frequency

### Primary pre-exposure immunisation:

For primary pre-exposure immunisation, three doses of rabies vaccine should be given on days 0, 7 and 28\*. The third dose can be given from day 21 if there is insufficient time before exposure.

Alternatively, an accelerated course may be given if there is insufficient time before exposure:

Three doses of rabies vaccine should be given on days 0, 3 and 7, with an additional dose at 12 months if continued exposure.

\*Where there is sufficient time to complete the 21-28 day course, this is the preferred schedule for those receiving pre-exposure prophylaxis.

### Reinforcing Immunisation:

For volunteer bat handlers with a likely frequency of ongoing exposures, a single reinforcing dose of vaccine should be given one year after the primary course has been completed. Further booster doses should then be given every three to five years or based on serology.

The cell-culture derived rabies vaccines may be used interchangeably to provide protection pre- or post- exposure.

## 2.5. Duration of treatment

See frequency section.

## 2.6. Maximum or minimum treatment period

See frequency section.

## 2.7. Quantity to supply/administer

One dose per occasion.

## 2.8. ▼ black triangle medicines

No.

## 2.9. Legal category

Prescription only medicine (POM).

## 2.10. Is the use outwith the SmPC?

The administration of the vaccine by deep subcutaneous injection to individuals with a bleeding disorder is outside the terms of the marketing authorisation and would be considered 'off-label' use of this vaccine. However, the use of the vaccine in this way is in line with recommendations in the Green Book [Chapter 27](#).

Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

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 NHS Board guidance on the storage and handling of vaccines or National 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.

## 2.11. Storage requirements

### General requirements

Vaccine should be stored at a temperature of +2° to +8°C.

Do not freeze.

During storage it is recommended that the vials are stored in the original packaging/cartons, away from direct sunlight to protect from light and kept upright.

NHS Board guidance on Storage and Handling of vaccines should be observed.

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 use or appropriate disposal.

## 2.12. Additional information

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation should be postponed until they have fully recovered.

Immunological response may be diminished in those receiving immunosuppressive treatment.

## 3. Adverse Reactions

### 3.1. Warnings including possible adverse reactions and management of these

Localised reactions such as redness, swelling or pain at the site of injection within 24 to 48 hours of administration.

Systemic reactions such as headache, fever, muscle aches, vomiting and urticarial rashes are rare. Reactions may become more severe with repeated doses.

Delayed hypersensitivity reactions have been reported from the US.

Neurological conditions, such as Guillain-Barré syndrome, have been reported extremely rarely; a causal association with immunisation is not established.

As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

In the event of a severe adverse reaction individuals should be advised to seek medical advice.

For full details/information on possible adverse reaction, refer to manufacturer's product literature or SmPC.

### 3.2. Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on <http://www.mhra.gov.uk/yellowcard>.

Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.

### 3.3. Advice to patient or carer including written information

Written information to be given to individual:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.

Individual advice / follow up treatment:

- Inform the individual/carer of possible side effects and their management.
- Advise of the need for immediate post-exposure first aid and seek medical advice for post exposure treatment, regardless of pre-exposure doses administered.

- Advise the individual on other preventative measures that may be implemented (i.e. avoid contact with animals).
- When applicable, advise individual/parent/carer when the subsequent dose is due.
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on:  
<http://www.mhra.gov.uk/yellowcard>
- Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine and they should continue to take appropriate measures to protect themselves against this infection.
- When administration is postponed advise the individual how future vaccination may be accessed.

### 3.4. Observation following vaccination

As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.

Following immunisation, patients remain under observation in line with NHS Board policy.

### 3.5. Follow up

See frequency section.

### 3.6. Additional facilities

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes.

The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

## 4. Characteristics of Staff Authorised Under the PGD

### 4.1. Professional qualifications

The following classes of registered healthcare practitioners are permitted to administer this vaccine:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC).
- pharmacists currently registered with the General Pharmaceutical Council (GPhC).
- pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC)
- chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC).
- dental hygienists and dental therapists registered with the General Dental Council.
- optometrists registered with the General Optical Council.

### 4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so. All persons operating this PGD:

- demonstrate appropriate knowledge and skills to work under this PGD.
- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it.
- must be familiar with the vaccine product and alert to changes in the manufacturer's product information/summary of product characteristics information.
- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent.
- must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions.
- must have access to the PGD and associated online resources.
- should fulfil any additional requirements defined by local policy.

Employer

- The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.
- As a minimum, competence requirements stipulated in the PGD must be adhered to.

### 4.3. Continuing education and training

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

- Have undertaken NoS PGD module training on [TURAS](#) Learn
- Have attended basic life support training either face to face or online and updated in-line with individual Board requirements
- Have undertaken immunisation training where available
- Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements
- Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.

## 5. Audit Trail

**Record the following information:**

- valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered if possible
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- batch number
- where possible expiry date
- anatomical site of vaccination
- advice given, including advice given if excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- administered under PGD

Records should be kept in line with local procedures.

Local policy should be followed to encourage information sharing with the individual's General Practice.

All records should be clear, legible and contemporaneous and in an easily retrievable format.

## 6. Additional References

Practitioners operating the PGD must be familiar with:

- [Immunisation against Infectious Disease \[Green Book\]](#).
- [Immunisation against Infectious Disease \[Green Book\] Rabies](#)
- [Professional Guidance on the Safe and Secure Handling of Medicines](#)
- [Professional Guidance on the Administration of Medicines in Healthcare Settings 2019](#)
- [Educational resources for registered professionals produced by National Education for Scotland](#)
- [Marketing authorisation holder's Summary of Product Characteristics](#)
- All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s)
- [Rabies pre- and post-exposure patient pathways](#)
- [Healthcare Improvement Scotland](#)



**Appendix 1 - Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction**

I: \_\_\_\_\_ (Insert name)

Working within: \_\_\_\_\_ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

**Patient Group Direction for the Administration of Rabies Vaccine for Bat Handlers by Approved Healthcare Professionals Working Within NHS Grampian, Orkney, Shetland, Tayside and Western Isles - Version 1.0**

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: \_\_\_\_\_

Print Name: \_\_\_\_\_

Date: \_\_\_\_\_

Profession: \_\_\_\_\_

Professional Registration number/PIN: \_\_\_\_\_



## Appendix 2 - Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

**The Lead manager/Professional** of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.

**The Senior Nurse/Professional** who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

**The Healthcare Professional** that is approved to administer the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.

### Patient Group Direction for the Administration of Rabies Vaccine for Bat Handlers by Approved Healthcare Professionals Working Within NHS Grampian, Orkney, Shetland, Tayside and Western Isles - Version 1.0

Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

