NHS Grampian | NHS Highland | NHS Orkney | NHS Shetland | NHS Tayside | NHS Eileanan Siar Western Isles

Patient Group Direction for the Administration of Rabies Vaccine for Travel by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: Adapted from PHS National PGD by the Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian

Signature:		**Signature:**

NoS Identifier: NoS/PGD/Travel_Rabies/ MGPG1263	**Review Date:** July 2024 **Expiry Date:** July 2025	**Date Approved:** July 2022

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 1

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD adapted from PHS national PGD for travel.	
Date of change	**Summary of Changes**	**Section heading**
March 2022	New PGD	

NoS Identifier: NoS/PGD/Travel_Rabies/MGPG1263
Keyword(s): PGD Patient Group Direction vaccine rabies Rabipur

Policy Statement:
It is the responsibility of the individual healthcare professional 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.

Document:	Drafted:	March 2022
	Completed:	July 2022
	Approved:	July 2022 (published – August 2022)
	Amended & reauthorized:	

Organisational Authorisations

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

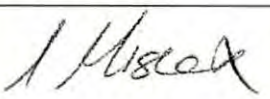
PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Dermot Gorman **Health Board:** NHSO **Title:** Consultant in Public Health **Contact email:** dermot.gorman@nhs.scot **Signature** ..... **Date:** 27/07/2022
Senior representative of the professional group who will provide care under the direction	**Name:** Mathew John Hamilton **Health Board:** NHSG **Title:** Community Pharmacy **Contact email:** matthewjohn.hamilton@nhs.scot **Signature** ..... **Date:** 28/07/2022
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** frances.adamson@nhs.scot **Signature** ..... **Date:** 26/07/2022
Pharmacist	**Name:** Russell Mackay **Health Board:** NHSO **Title :** Clinical Pharmacist **Contact email:** russell.mackay@nhs.scot **Signature** ..... **Date:** 27/07/2022

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		26/07/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		03/08/2022

Management and Monitoring of Patient Group Direction

PGD Consultative Group

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

Name:	Title:
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse NHSG
Russell Mackay	**Pharmacist:** Clinical Pharmacist NHSO
Dr Dermot Gorman	**Medical Practitioner:** Consultant in Public Health NHSO
Mathew John Hamilton	**Senior Representative:** Community Pharmacist NHSG
Mary McFarlane	Principal Pharmacist NHSS
Andrew Radley	Consultant in Public Health Pharmacy
Liam Callaghan	Chief Pharmacist NHSWI

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Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer rabies vaccine for pre-exposure and reinforcing immunisations of individuals considered to be at risk of exposure to the rabies virus related to travel. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book Chapter 27, TRAVAX, NaTHNaC and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	• Individuals who intend to travel to or reside in countries where rabies vaccination is currently recommended for travel in accordance with national recommendations issued by TRAVAX www.travax.nhs.uk/destinations/ The risk of exposure should be determined after careful risk assessment of an individual's itinerary, duration of stay, planned activities and medical history. Both rabies vaccine BP and Rabipur® are indicated for the active immunisation against rabies in individuals of all ages. Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	Individuals who: • 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*, human serum albumin, neomycin, chlortetracycline and amphotericin B (refer to relevant SmPC). • Are at increased risk of rabies infection solely because of their occupation, refer to their employer's occupational health provider for vaccination. • Require vaccination unrelated to travel purposes.

	• 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. • Have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free. • Where there is no valid consent. *****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.
Precautions and special warnings	Minor illness without fever or systemic upset is not a valid reason to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. The Green Book advises there are very few individuals who cannot receive rabies containing vaccines. When there is doubt, appropriate advice should be sought from an immunisation co-ordinator or consultant in communicable disease control rather than withholding the vaccine. Individuals with immunosuppression or HIV infection can be given rabies containing vaccines although these individuals may not make a full antibody response. Immunological response may be diminished in those receiving immunosuppressive treatment. 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. 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.
Action if excluded from treatment	Specialist advice must be sought on the vaccine and circumstances under which it could be given as immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.

	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. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged. Individuals who have had a confirmed anaphylactic reaction to a previous dose of a rabies containing vaccine or any components of the vaccines should be referred to a clinician for specialist advice and appropriate management. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached. 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 that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.

Description of vaccine available under the PGD

Name form and strength of vaccine	Rabies vaccine is available as either; Rabies Vaccine BP human diploid cell vaccine powder and solvent for suspension for injection. After reconstitution, 1 dose (1mL) contains: Rabies virus (inactivated, strain PM/WI 38 1503-3M) ≥2.5IU. Or Rabipur® purified chick embryo cell rabies vaccine powder and solvent for suspension for injection. After reconstitution, 1 vial (1mL) contains: Rabies virus (Inactivated, strain Flury LEP) ≥ 2.5IU.

Legal status	Rabies Vaccine is a Prescription-only Medicine (POM). Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS board guidance on storage and handling of vaccines guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed. The administration of Rabies Vaccine BP/Rabipur® by deep subcutaneous injection to individuals with a bleeding disorder is outside the terms of the marketing authorisation and constitutes an off-label use of the vaccine. However, the use of the vaccine in this way is in-line with recommendations in the Green Book Chapter 27 and Chapter 4. The individual or the person with parental responsibility should be informed prior to the administration that the use is off-label.
Dosage/Maximum total dose	1mL
Frequency of dose/Duration of treatment	**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 travel. Alternatively, an accelerated course may be given if there is insufficient time before travel: • Three doses of rabies vaccine should be given on days 0, 3 and 7, with an additional dose at 12 months if continued to travel to high risk (enzootic) areas. *****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:** Routine booster doses are not recommended for most travellers. A one -off booster dose of vaccine can be considered, following a risk assessment, in those who have completed a primary course over one year ago and are again intending to travel to or reside in countries where rabies vaccination is currently recommended for travel in accordance with national recommendations issued by TRAVAX www.travax.nhs.uk/destinations/.
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.

Route/Method of administration	Rabipur® is for intramuscular administration only. For adults and children ≥ 1 years of age, the vaccine should be administered into the deltoid muscle. For children <1 year, the anterolateral area of the thigh is recommended. Rabies Vaccine BP is administer by intramuscular injection. The vaccine should be administered into the deltoid region. The Green Book recommends for children <1 year of age the anterolateral area of the thigh be used. For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given in accordance with the recommendations in the 'Green Book' Chapter 4 When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for each of the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to Rabies Vaccine BP/Rabipur®. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individual's records. **Rabies vaccine BP** The vaccine is supplied as freeze-dried powder and solvent for suspension and for injection. The powder is pinkish beige to orangey yellow. The solvent is a clear, colourless solution. Following reconstitution with the solvent supplied, the suspension will be a pinkish colour and free from particles. **Rabipur®** The vaccine is supplied as freeze-dried powder and solvent for suspension and for injection. The powder is white. The solvent is a clear, colourless solution. Following reconstitution with the solvent supplied, the suspension will be a clear-colourless solution and free from particles. Both vaccines should be used immediately and no later than one hour after reconstitution with the solvent supplied. 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.
Quantity to be administered	1mL dose per administration.

Storage requirements	Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Do not freeze. Store in original packaging in order to protect from light. Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also 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 off-label use or appropriate disposal.
Follow-up (if applicable)	Following immunisation patients should remain under observation in line with individual NHS Board policy. Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice. Where proof of vaccination is required, a certificate, stamped vaccination booklet or equivalent must be supplied.
Advice (Verbal)	Advise individual/person with parental responsibility what to expect and what to do for minor and major reactions. Advise of the need for immediate post-exposure first aid and seek medical advice for post exposure treatment, regardless of pre-exposure doses administered. If serious adverse or persistent effects occur, the individual/person with parental responsibility should be advised to contact their GP/Accident and Emergency department/NHS24. When administration is postponed advise the individual/person with parental responsibility when to return for vaccination. If appropriate, advise the individual/person with parental responsibility when subsequent doses are due and if any follow up is required.

Advice (Written)	The PIL contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Further information on travel health is available at https://www.fitfortravel.nhs.uk/home.
Identifying and managing possible adverse reactions	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. The most commonly seen reactions are minor local injection site reactions such as hardening of the skin, oedema, pain and redness. A small painless nodule may form at the injection site. 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. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc)

	If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System. Yellow Card Scheme - MHRA
Facilities and supplies required	The following are to be available at sites where the vaccine is to be administered: • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit) • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this PGD in print or electronically

Characteristics of staff authorised to administer vaccine under PGD

Professional qualifications	Those registered healthcare professionals that are listed and approved in legislation as able to operate under Patient Group Directions, as identified and included in individual Board immunisation delivery plans.
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's/person with parental responsibilities capacity to understand the nature and purpose of vaccination in order to give or refuse consent • Competent to undertake administration of the vaccine and discuss issues related to vaccination • Competent in the handling and storage of vaccines, and management of the "cold chain" • Competent to work under this PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • 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 • Have knowledge and familiarity of the following; o Current edition of the Green Book o SmPC for the vaccine to be administered in accordance with this PGD o Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board o Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.

Documentation

Authorisation of administration	Qualified health professionals working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles listed and approved in legislation as able to operate under PGD can be authorised to administer the vaccine specified in this PGD in accordance with local delivery plans and by agreement at individual Board level as per the following: Nurses, midwives and health visitors can be authorised by their line manager. Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they

	have completed local Board requirements for service registration. The following list of healthcare professionals can be authorised by their Line Manager, Head of Service or Vaccine Coordinator: Chiropodists, dental hygienists, dental therapists, dieticians, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists. All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.
Record of administration	An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the vaccine specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum: • Date and time of vaccine administration • Individuals name and CHI • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, brand, dose, form, batch number, expiry date, route/site of the vaccination administered • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine • Record of any adverse effects (advise individuals GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate. • Individual service specific systems.
Audit	All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.

References	Electronic Medicines Compendium http://www.medicines.org.uk Rabies Vaccine BP– Date of revision of text18/06/20, accessed16/03/22. Rabipur® - Date of revision of text 01/02/21, accessed 16/03/22. British National Formulary for Children and the British National Formulary https://about.medicinescomplete.com/ accessed 15/03/22. Department of Health (2006): Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book Rabies: the green book, chapter 27 - GOV.UK (www.gov.uk) American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

Patient Group Direction for the Administration of Rabies Vaccine for Travel by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

I have completed the appropriate training to my professional standards enabling me to administer the vaccine 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 _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2

Healthcare Professionals Authorisation to Administer Vaccine 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 vaccine under this PGD is responsible for ensuring that he or she is 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 vaccine under this PGD is responsible for ensuring that he or she understands and is 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 his or her individual code of professional practice and conduct.
Patient Group Direction for the Administration of Rabies Vaccine for Travel by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles
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

Patient Group Direction for the Administration of Rabies Vaccine for Travel by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**