



Centre for Infections
CLINICAL RABIES SERVICE
April 2010

Cfl Clinical Rabies Service April 2010

A. Clinical Risk Assessment & Evaluation of Susceptibility

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Key questions for duty doctors to ask to make clinical decisions

Is the query about:

- a possible case of acute rabies ? (Refer to VRD Consultant)
- possible exposure to rabies through animal contact (post exposure)
- vaccines prior to travel (refer NathNAC website <http://www.nathnac.org>, or for complex queries advice line 0845 602 6712)
- vaccines for those with occupational risk (p14)

Post Exposure Risk Assessment: does the person need post exposure prophylaxis?

1. Which animal

- Bat
- Terrestrial animal

2. Which country

3. Date of exposure

4. Type of exposure

Contact

No direct physical contact

5. Can animal be observed

6. Has the person been vaccinated

7. Location of person

UK
London
Out of UK

A.1 Information about animals

“The most frequent way that humans become infected with rabies is through the bite of infected dogs and cats, wild carnivorous species like foxes, raccoons, skunks, jackals and wolves, and insectivorous and vampire bats. Cattle, horses, deer and other herbivores can become infected with rabies and although they could potentially transmit the virus to other animals and to people, this rarely occurs.”¹

Decision Points

What species? Was it a terrestrial mammal or a bat?

Bats

Bats may carry rabies and related lyssaviruses without signs of disease. Therefore exposure to bats or their secretions may constitute an exposure to virus in countries which are declared rabies free in terrestrial animals. In the UK, bats are the **ONLY** reservoir of rabies or related lyssavirus, but they are a protected species and cannot be destroyed to determine rabies status if caught.

HPA recommendation is that post exposure prophylaxis for bat exposure should **include vaccine plus or minus RIG** (according to risk assessment) in an unvaccinated person wherever in the world this has occurred.

Domestic dogs and cats: Observation of animal

The natural history of rabies in companion dog and cats is that an animal shedding rabies virus through its saliva will be in the terminal phase of illness, and is unlikely to be behaving normally. **If the animal is observed and remains well and behaves normally 15 days after a biting incident, it will not have rabies infection.**

Rodent and primate bites

Rabies infected rodents and primates have been sporadically described in countries where rabies is endemic. Although the risk of transmission of rabies from a rodent or primate bite is extremely low, rodent and primate bites occurring in low or high risk countries should receive post exposure prophylaxis with **vaccine only**.

Further Information (useful but not essential)

If the animal was a terrestrial mammal (wild or domestic):

- Is rabies known or suspected to be present in the species in the locality?
- Is there an owner known and contactable?
- Was the animal behaving normally at the time of the incident?
- Had it been immunised?
- If the animal was a dog or a cat did it become ill while under observation?
- If the animal has died, does laboratory examination of the animal's brain confirm rabies

¹ <http://www.who.int/mediacentre/factsheets/fs099/en/>

A.2. Which country? (No risk / low risk / high risk)

Background

Article 2.2.5.2. of the Terrestrial Animal Health Code (2007) http://www.oie.int/eng/normes/Mcode/en_sommaire.htm describes a rabies free country.

A country may be considered free from rabies when:

1. the disease is notifiable;
2. an effective system of disease surveillance is in operation;
3. all regulatory measures for the prevention and control of rabies have been implemented including effective importation procedures;
4. no case of indigenously acquired rabies infection has been confirmed in man or any animal species during the past 2 years; however, this status would not be affected by the isolation of a bat lyssavirus such as European Bat Lyssavirus (EBL1 or EBL2);
5. no imported case in carnivores has been confirmed outside a quarantine station for the past 6 months.

The risk of rabies according to geographical location (country, island and territory) is updated regularly and the most recent version can be found on the HPA website at: http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1259152458758.

Decision Points

Where did the incident take place and on what date?

Further information (may affect risk assessment)

Is the animal non-indigenous or imported? If imported, from where?

If the animal was a terrestrial mammal, it is important to determine the risk of rabies (no risk / low risk / high risk) in the country of potential exposure and the country of origin of the animal.

Is rabies known or suspected to be present in the country of

- Potential rabies exposure?
- Origin of the animal? (if the animal is non-indigenous or recently imported)

A.3 Nature of exposure?

Terrestrial Mammals: Decision Point
Need to decide if there has been direct physical contact
(Yes/No)

Category	Terrestrial Mammal: Nature of exposure (Adapted from WHO and DOH)
I	Touching or stroking animals
II	Licks of the skin or other contact with saliva (e.g. feeding animals) Minor scratches, bruising or abrasions without bleeding Minor bites without breaking of the skin (covered areas of arms, trunk, and legs) All bites, licks and scratches from rodents and primates
III	Single or multiple transdermal bites or scratches, licks on broken skin Major bites (multiple or on face, head, finger or neck) Contamination of mucous membrane with saliva (i.e. licks)

Further Information (useful but not essential)

- The site and severity of the wound
- The circumstances of the bite (or other contact)
- The species, behaviour and appearance of the animal
- The vaccination status of the animal
- The origin of the animal

Bats: Decision Point
Need to decide what kind of contact (Indirect/Direct)

Category	Bats: Categories of exposure (Adapted from WHO, HPS and DOH)
I	No physical contact: i.e. no direct physical contact with the bat's saliva or neural tissue, or if the person was protected by a barrier capable of preventing such contact, such as a boot, shoe, or appropriate protective clothing
II	Indirect physical contact (may be common with bat exposures): i.e. where there has been no observed direct physical contact, but this could have occurred, for example bat tangled in hair or found in the room of sleeping child or person under the influence of drugs/ alcohol.
III	Direct physical contact: <ul style="list-style-type: none"> • Single or multiple transdermal bites or scratches & bruising • Minor bites without breaking of the skin (covered areas of arms, trunk, and legs) • Major bites (multiple or on face, head, finger or neck) Contamination of mucous membrane with saliva or bat droppings/urine

NB 50% of human cases in recent years in the USA have resulted from unrecognised bat bites. Bat bites may not cause an obvious break in the skin, but should still be considered a definite physical exposure (category III)

A.4 Assessment of Rabies Immune Status

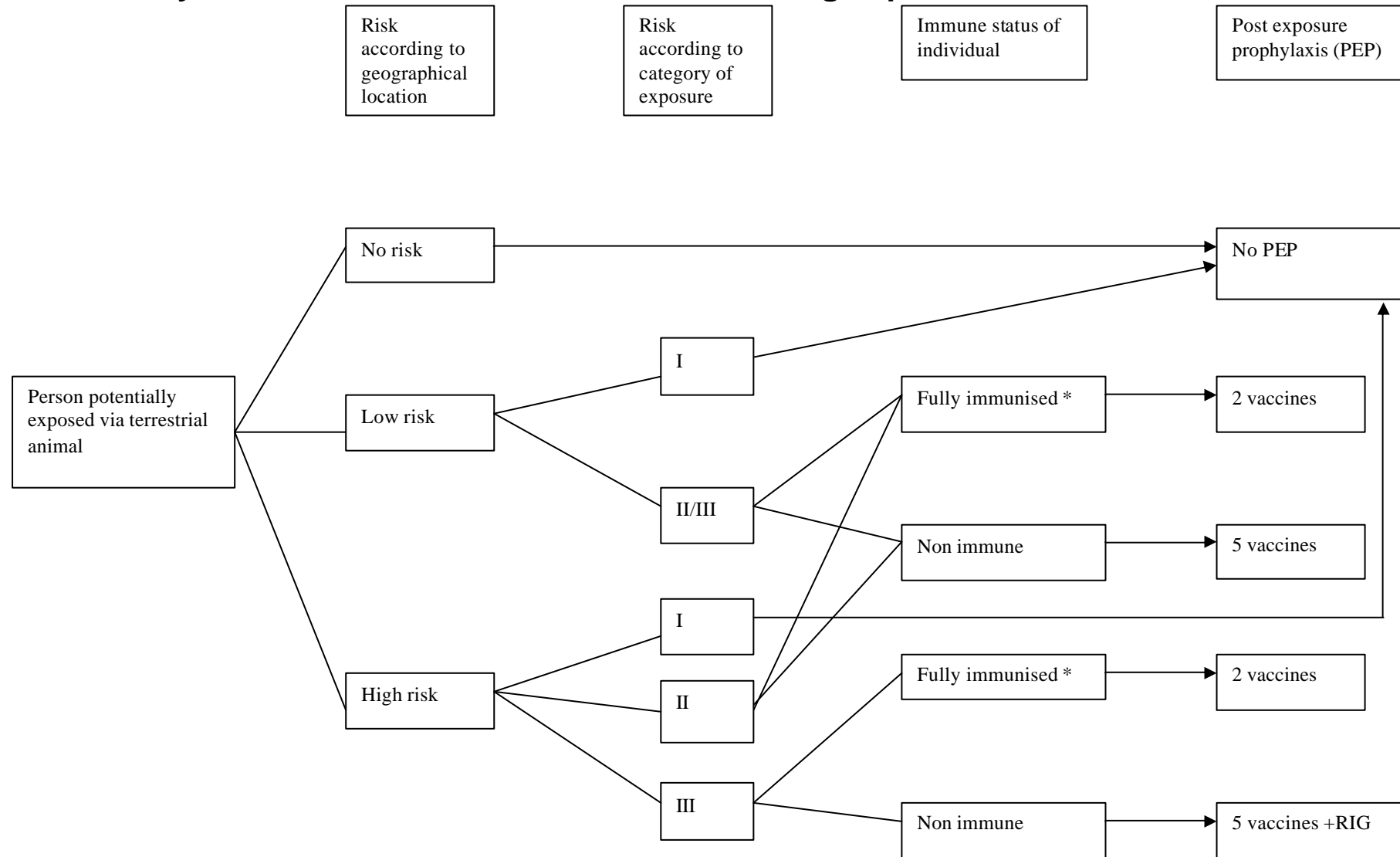
Decision Points
Need to decide whether immune or non immune

Status of the individual for post-exposure prophylaxis	Description
Non immune	<ul style="list-style-type: none"> • Person who has never received pre- or post-exposure immunisation with rabies vaccine or, • Has had incomplete/inadequate primary vaccination course
Fully immunised*	<ul style="list-style-type: none"> ▪ At least 3 documented doses i.m. of rabies vaccine: this may either be a complete primary pre-exposure course or part of a post exposure course (and includes those where subsequent boosting has occurred), or ▪ Documented rabies antibody (VNA) titres of at least 0.5 IU/ml.

* in individuals whose last dose of vaccine was more than 5 years previously and there are particular risk factors (a known rabid animal or multiple severe bites to the head and neck) then specialist advice should be sought from VRD. Depending on individual risk assessment additional vaccine +/- HRIG may be considered.

If in doubt, treat as non immune.

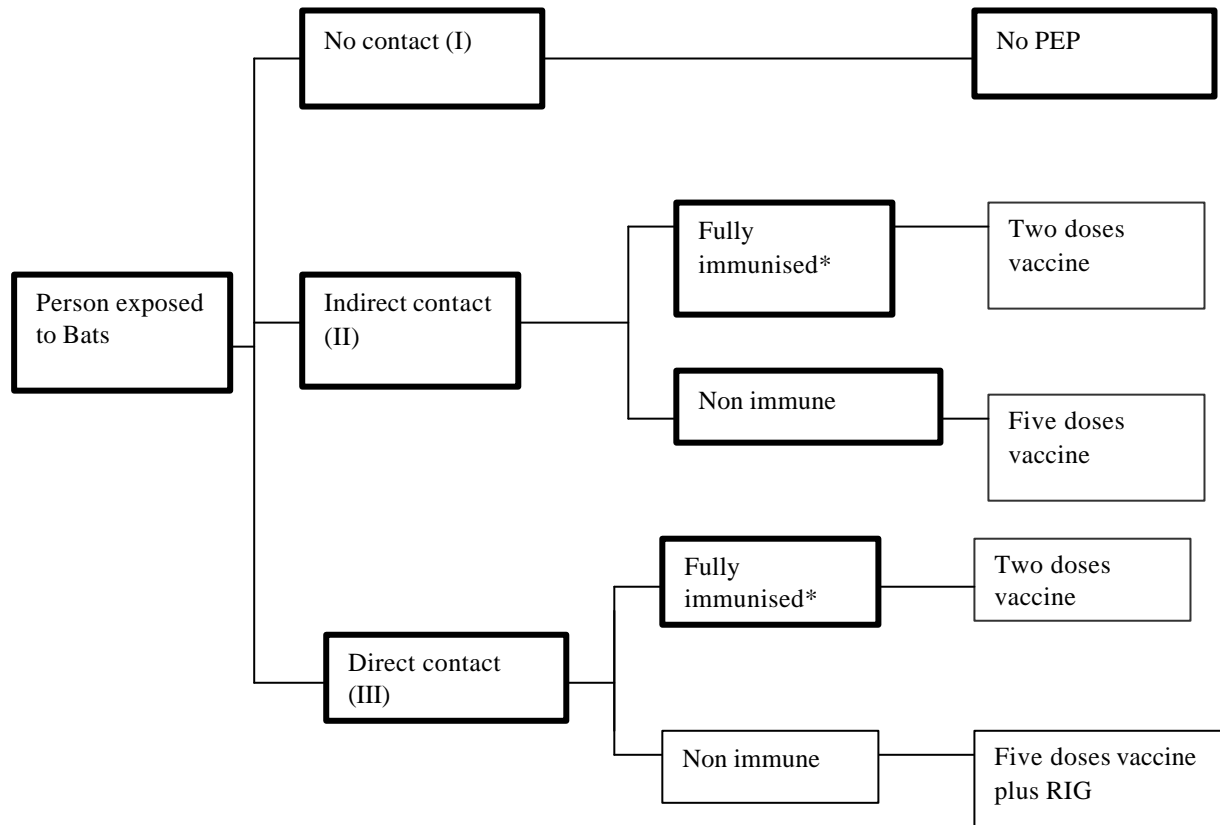
Summary of Risk Assessment Treatment following exposure to terrestrial animals



* in individuals whose last dose of vaccine was more than 5 years previously and there are particular risk factors (a known rabid animal or multiple severe bites to the head and neck) then specialist advice should be sought from VRD. Depending on individual risk assessment additional doses of vaccine +/- HRIG may be considered.

Summary of Risk Assessment for Treatment following Bat Exposure

NB All countries should be considered high risk for all bat species



* in individuals whose last dose of vaccine was more than 5 years previously and there are particular risk factors (a known rabid animal or multiple severe bites to the head and neck) then specialist advice should be sought from VRD. Depending on individual risk assessment additional doses of vaccine +/- HRIG may be considered.

B.1 Types of Rabies Vaccine used globally for Rabies PEP

Decision Points
Is the vaccine compatible with UK schedule (Yes/No)

Rabies Vaccine	Comment	Manufacturer & likely distribution	Compatible with UK
Human diploid cell vaccine (HDCV)	Immunogenicity efficacy data do exist for this	IMOVAX Pasteur Mérieux Group, Sanofi Pasteur MSD Ltd UK)	v
Purified chick embryo cell vaccine (PCECV)	Immunogenicity efficacy data do exist for this	(UK licence) Chiron Vaccines	v
Purified vero cell vaccine (PVRV)	Vaccine is made on mammalian cells (VERO cells) as an alternative cell substrate to fibroblast cells. This is a licensed vaccine produced in many parts of the world (although unlicensed in the UK), for which formal efficacy data do not exist, but the potency and immunogenicity is evaluated similarly to HDCV and PCECV vaccines. These are generally reliable vaccines.	Variety of manufacturers make this...Possible trade names include VERORAB. ABHAYRAB (India) SII Rabivax (India) Speeda (CELBIO)	v
Suckling Mouse Brain vaccine (SMBV)	Vaccines of this sort generally reliable but may have marginally reduced efficiency with increased risk of side effects.	Used in S America	X
Nervous tissue vaccine (sheep, goat)	Vaccines of this sort generally reliable but may have marginally reduced efficiency with increased risk of side effects.	Used in Asia but being phased out	X
Horse Serum	Trade name not clear. May be given as treatment alone or with vaccine. Most often found in certain S America countries. If this is the only treatment given, need to start PEP (Omit RIG)	Unknown	X

B.2 Regimen (Timing) of Vaccine

- The UK schedule is 5 vaccines at the following interval 0, 3, 7, 14, 28-30 days.
- Day 0 is the day of 1st vaccine NOT necessarily day of exposure.
- UK schedule until 2000 or earlier included a day 90 vaccine. This is now no longer required.
- We do not routinely measure rabies antibody titres, for reasons of expense and practicality. If there is no clinical indication for testing the cost will need to be borne by the patient or requesting health facility. If an individual is insistent on this in the absence of clinical indications the cost is approximately £50 and they should contact VLA (Rabies Help Line Monday to Friday 9am to 5pm 01932 357345, or main number 01932 341111)
- If a dose is missed, or timing has been compromised, the next vaccine should be considered as the missed dose, and subsequent intervals readjusted.
- The 5th final dose of rabies vaccine PEP should not be given before day 26.
- If a person is travelling with difficulty in achieving the specified interval for PEP, it is most important to deliver the first 3 vaccines with plus/minus one day.
- In a patient who is fully immune at the time of exposure the UK schedule is 2 vaccines at 0 and 3-7 days.

B.3 Route of Vaccine Delivery

- Although i.m and id routes of delivery are considered to be acceptable, id administration requires more experience and if given incorrectly may result in reduced vaccine efficiency. As a consequence, all UK scheduled for PEP recommend i.m administration.
- If a person has commenced id elsewhere and wishes to complete treatment in UK the following options may be considered.

1. Recommence UK schedule de novo (omit RIG)
2. Complete UK Schedule

Discussion about options with VRD on case-by case basis.

B.4 Interchangeability of Vaccines

Decision Points
Is it necessary to start a new vaccine course on return to UK?
(Yes/No)

There are several things to consider:

1. Type of vaccine
2. Regimen
3. Route of delivery (intra-dermal (id) vs. intra-muscular (i.m))

Type of vaccine

In the UK there are two licensed vaccines in use. These can be safely interchanged, and efficacy data exist for both of these vaccines:

1. Human Diploid Cell (HDCV) rabies vaccine BP [Sanofi Pasteur]. This is grown on human fibroblast cell substrate.
2. Purified chick embryo cell rabies vaccine (PCECV) RABIPUR [Chiron/Novartis].

During recent shortages of licensed vaccine Purified vero cell vaccine (PVRV) VERORAB [Sanofi Pasteur] has also been available in the UK. Whilst this is currently unlicensed in the UK it is approved for use by the MRHA and is available on a named patient basis.

Table 1 provides a generic classification of types of vaccine available globally and their compatibility with UK vaccines. When providing advice about the interchangeability of different vaccines, and trying to work out what to do if there is a partially completed course of PEP started abroad, the following are clues to assist decision making

- Most vaccines available in Europe, N America, Australia, and New Zealand are either HDCV, PCECV or vaccines grown on mammalian cells (PVRV).
- Vaccine issuing centres, including Cfl, usually only hold one sort of vaccine (depending on availability), either HDCV, PCECV, or PVRV which will be the only possible vaccine that can be issued. If an individual insists on a particular type of vaccine not held within the HPA supply, this will have to be sourced and paid for privately by that individual.
- If vaccine compatible with UK schedule, then convert timing of doses to closest UK vaccine dose.
- If a vaccine course has been started /completed with a vaccine NOT compatible with UK schedule, there are several options.

1. If schedule has involved multiple injections (e.g. as per S America nervous tissue vaccines) consider obtaining antibody titre before restarting UK PEP.
2. If partially completed schedule consider whether to
 - a) restart UK PEP (omit RIG) or
 - b) complete on UK schedule and then test antibodies

Discussion about options with VRD on case-by case basis.

B.5 Pre Exposure Immunisation

Immunisation against infectious diseases 2006 (Green book) lists criteria for provision of vaccine from Cfl for pre exposure immunisation for certain categories of people travelling abroad and those occupationally exposed.

- Cfl does NOT provide pre exposure for travellers without an occupational risk. Travel advice calls should be referred to NATHNAC 0845 602 6712.
- Cfl does NOT provide Rabies vaccine for vets/animal workers outside defined criteria in green book.
- Request for provision of pre exposure vaccine for these falling into defined categories must be made in writing to rabies clerk by fax or surface mail (include contact details). These will be authorised by a duty doctor. There is no urgency to such requests and vaccine for pre exposure immunisation is never issued out of hours.

UK Schedule for those at potential ongoing occupational risk (e.g. bat handlers)

- The recommended schedule for primary vaccination is 3 doses, each of 1.0ml given intramuscularly (deltoid), day 0, 7, 28.
- The earliest day that 3rd dose can be given to achieve effective immune status is day 21.
- The first booster following a primary course of vaccine should be at 1 year in the first instance with subsequent boosting between 3-5 years.
- Antibody quantification is generally not required, but one may need to consider this option if individuals are seriously immunocompromised.
- The 2006 changes to UK pre-exposure schedule involved the introduction of booster at 1year following a primary course, without antibody testing. This has now replaced previous advice regarding testing antibody levels.
- If individuals insist on antibody levels being measured when this is not clinically justified, the cost of this will be £50 to the individual and should be arranged directly with VLA (Rabies Help Line Monday to Friday 9am to 5pm 01932 357345, or main number 01932 341111).
- Alternative schedules advised from other countries, or through the internet, are not recommended in the UK.

B.6 Rabies Immunoglobulin (RIG)

- The mainstay of rabies post exposure prophylaxis (PEP) is rabies vaccine. Rabies Immune Globulin (RIG) may provide short term immunity in the first 7 days post initiation of treatment.
- The total antibody level induced by active immunisation (vaccine) is many orders of magnitude greater that can be provided by passive immunisation (RIG). For this reason RIG is not given after 7 days post initiation of rabies PEP schedule or to an individual who is already partially immunised.
- RIG is manufactured from non UK blood products. The final formulation is a liquid and the potency of the material is assessed in international units (IU/ml). The recommended dose is 20 IU/kg, adults and children (all age)
- The preparations of RIG available for dispensing from Cfl do vary in potency and volume. It is therefore CRITICAL to know the following:
 1. The potency of the current batch in use. Different manufacturers describe the potency in different ways, and RIG batches from the same manufacturer vary in potency. The description of potency **on a vial from BPL** indicates the volume needed to administer 500IU. Except where the potency is exactly 500IU/ml, this will **NOT be the same as IU/ml**. Vials usually contain between 1 and 2 mls of liquid and will always contain slightly more volume than required to administer 500IU. Berirab-P vials have the potency described in IU/mL. Information about potency of batches is available from rabies clerk (Cfl x6204), who together with Theresa Gibbs in the Immunisation Department (Cfl X 7472) is responsible for notifying all Cfl doctors and stockholders outside Cfl when batches are received with a change in potency or manufacturer.
 2. Weight of patient
 3. Volume in vials (vials contain between 1- 2mls, depending on batch and manufacturer of RIG)

The correct volume for each patient should be calculated and indicated on the supplied proforma which is issued to the health care provider with the RIG.

Worked example 1

Child wt 19kg, BPL Potency is 500IU/1.1mls, vials contain 2.2mls

- Required units total = $20 \times 19 \text{ IU} = 380\text{IU}$
- Need to administer $(380 \times 1.1)/500 = 0.8\text{mls}$
- Need to supply 1 vial, there will be some wastage

Worked example 2

Adult wt 85kg BPL Potency is 500IU/1.1mls, vials contain 2.2mls

- Required units total = $85 \times 20 = 1700$
- Need to administer $(1700 \times 1.1)/500 = 3.7\text{mls}$
- Need to supply 2 vials

Worked example 3

Adult wt 70 kg Berirab-P potency is 150 IU/mL, vials contain 2 mls

- Required units total = $70 \times 20 = 1400$
- Need to administer $1400/150 = 9.3\text{mls}$
- Need to supply 5 vials

B.7 Administering Vaccine & Immunoglobulin

- Vaccine is given in the deltoid muscle by intramuscular injections. Each sequential dose should be given in alternate deltoids. Suggest start in non dominant arm.
- All immunoglobulin (RIG) is given at the site of the wound, infiltrated intramuscularly around the site of the wound. If this is difficult or the wound has completely healed, then this can be given in the anterolateral thigh (this advice is based on the most recent WHO position paper on rabies vaccine (Dec 2007) and may contradict advice in rabies immunoglobulin product leaflet, which has not been updated).
- If more than 5mL (2mL in children under 20 kg) of RIG needs to be administered it should be in divided doses, at different sites
- Vaccine and RIG should NEVER be given at the same anatomical site.
- Adverse reactions to vaccine and immunoglobulin are briefly discussed in the Green Book P340.

B.8 Leaflet Accompanying Vaccines and Immunoglobulin Issued from Cfl

Administration of Rabies Vaccines & Immunoglobulins

Post Exposure Vaccine

- Post Exposure Prophylaxis (PEP) vaccine is administered intramuscularly in the deltoid muscle
- The UK schedule for unimmunised individuals is 5 vaccines (+/- RIG) at the following interval 0, 3, 7, 14, 28-30 days
- Each sequential dose should be given in alternate arms. Suggest start in non dominant arm
- Day 0 is the day of 1st vaccine NOT necessarily day of exposure
- If a dose is missed, or timing has been compromised, the next vaccine should be given as soon as possible and considered as the missed dose, and subsequent intervals readjusted
- The 5th final dose of rabies vaccine PEP, should not be given before day 26
- If there is difficulty in achieving the specified interval for PEP, it is most important to deliver the first 3 vaccines with plus/minus one day
- Altered vaccine PEP schedules for partially immune individuals may need to be discussed on an individual basis.

Rabies Immunoglobulin (RIG)

- RIG is given in addition to vaccine depending on risk assessment of exposure to provide short term protection in the first 7 days post initiation of treatment
- The total antibody induced by active vaccination (vaccine) is many orders of magnitude greater that can be provided by passive vaccination (RIG). For this reason RIG is not given after 7 days post initiation of rabies PEP vaccine schedule or to an individual who is already partially immunised
- RIG is infiltrated intramuscularly around the site of the wound if possible. If this is difficult or the wound has completed healed, then RIG can be given in the anterolateral thigh
- Vaccine and RIG should **NEVER** be given at the same anatomical site
- RIG is manufactured from non UK blood products. The final formulation is a liquid and the potency of the material is assessed in international units (IU/ml)
- The recommended dose is 20 IU/kg (all ages)
- RIG batches from the same manufacturer do vary in potency. It is therefore **CRITICAL** to know the following
 - Potency
 - Weight of patient
- The potency is given in IU/mL. It is necessary to calculate the required volume
- If more than 5 mL (2 mL in children under 20 kg) of RIG is needed, it should be given in divided doses at different sites.
- Adverse reactions to vaccine and immunoglobulin are briefly discussed in the Department of Health Immunisation against Infectious Diseases 2006 3rd Edition Green Book p340

C.1 Issuing Rabies Vaccines from Cfl

General

- Vaccines are held in Cfl (Cold Room 1A35) and are issued by the rabies clerk on receipt of doctor authorisation/proforma (available on rabies page of Duty Doctor pack) with patient details (Table C2)
- On call /Duty BMS will issue rabies vaccine for collection out of hours (Table C2). Proforma for the issue should be provided to rabies clerk the next working day
- Rabies vaccines are packaged with cold packs and distributed via guaranteed postal delivery or Rabies vaccines can be collected at any time (24/7) from reception at Cfl.
- Rabies clerk requires forms by 3.30pm to ensure sufficient packaging time to meet collection time of 4pm for guaranteed next day delivery
- Vaccines are also held in various centres across UK (supply list). It may be more convenient to issue from alternative supply centre, once decision has been made that vaccine/immunoglobulin are appropriate. However vaccine supply centres elsewhere may be used for collection of vaccines and RIG, but do not provide postal delivery
- Vaccines (but not RIG) can be obtained from pharmacies on prescription

LOGISTIC INFORMATION

- HPA/Dept Health does not supply rabies vaccines for Scotland or N Ireland. Requests from Scotland should be referred to Health Protection Scotland (0141 300 1100), and from Northern Ireland to the Public Health Laboratory, Belfast City Hospital (028 9032 9241).
- We do not supply **by post** rabies vaccines on a Friday or before Bank Holiday (unless guaranteed person to receive at destination (GP Surgery/AE Dept).
- We do not provide couriers for vaccine. Arrangements for collection are either organised individually with the patient or via local health facility responsible for treating patient.
- We do not issue vaccines or RIG for people currently out of the UK.
- If people are travelling with vaccines, vaccine must be kept cold (4°C) with an ice pack or in a domestic fridge at all times and if it is envisaged that an individual will be more than 24 hours in transit, vaccine should not be issued. More than 24 hours at room temperature renders a loss of potency of vaccine .
- Patients should be advised that it may not be possible for security reasons to travel on planes with vaccines in hand luggage.
- Vaccine may need to be sourced locally in different countries as doctors may refuse to give unfamiliar vaccine products brought from the UK.

C.2 National Issuing Centres Rabies Vaccines and Rabies Immunoglobulin

Current issuing centres in England and Wales are in:

- Birmingham
- Cambridge
- Cardiff
- Exeter
- Heathrow Airport
- Leeds
- Liverpool
- Oxford
- Newcastle
- Norwich
- Southampton

Source Documents & useful references

HPA Public Health Management of suspected case of Human rabies, A standard operating procedure for communication and action 30/11/2004

Management of rabies in humans: Jackson et al (2003) CID 36 60-63

A fatal encephalitis : Schankin et al (2005), Lancet **365** 358-359

DH memorandum on rabies: Memorandum on Rabies Prevention and Control (Feb 2000)

http://www.dh.gov.uk/prod_consum_dh/idcplg?IdcService=GET_FILE&dID=949&Rendition=Web

Immunisation against infectious disease - "The Green Book"

http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH_4097254

WHO Expert Consultation on rabies

WHO expert consultation on rabies. First report. Geneva, World Health Organization, 2005 (WHO Technical Report Series No. 931; ISBN 92 4 120931; http://www.who.int/rabies/trs931_%2006_05.pdf)

WHO expert consultation on rabies. First report. Geneva, World Health Organization, 2005 [WHO Technical Report Series No. 931; ISBN 92 4 120931](http://www.who.int/rabies/en/WHO_guide_rabies_pre_post_exp_treat_humans.pdf)

http://www.who.int/rabies/en/WHO_guide_rabies_pre_post_exp_treat_humans.pdf

http://www.oie.int/eng/normes/mcode/en_chapitre_2.2.5.htm

<http://www.who.int/entity/immunization/policy/rabies.pdf>

<http://www.who.int/mediacentre/factsheets/fs099/en/>

http://www.who.int/rabies/en/Intradermal_application_of_rabies_vaccines.pdf

Current WHO Guide for Rabies Pre and Post Exposure Treatment in Humans

WHO position paper :Rabies vaccines :Weekly Epidemiological Record (WER) [7 December 2007](http://www.who.int/wer), vol. 82, 49/50 (pp 425–436)

Terrestrial animal health code

http://www.oie.int/eng/normes/Mcode/en_chapitre_2.2.5.htm

British National Formulary

<http://www.bnf.org>

Safety review of purified chick embryo cell rabies vaccine: Data from Vaccine Adverse Event Reporting System 1997-2005. Dobaric et al, Vaccine 25 (2007) 4244-4251

Rabies Antibody levels in Bat Handlers in the UK Morris et al, 2007 Human Vaccines 3:5 165-170

Many of these are available on the Rabies page of the Duty Doctor pack on the Intranet