Government of **Western Australia**
Department of **Health**

Protocol for accessing immunoglobulins and antitoxins for public health indications in Western Australia

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Abbreviations

Abbreviation	Definition
ABLV	Australian bat lyssavirus
BabyBIG	Botulinum immunoglobulin for infant botulism
BAT	Botulinum antitoxin
CDCD	Communicable Disease Control Directorate
CDNA	Communicable Diseases Network Australia
DAT	Diphtheria antitoxin
DPIRD	Department of Primary Industries and Regional Development
ED	Emergency department
HRIg	Human rabies immunoglobulin
NHIg	Normal human immunoglobulin
PHP	Public health physician
SoNG	Series of National Guidelines
TGA	Therapeutic Goods Administration
US FDA	United States Food and Drug Administration
WA	Western Australia
ZIg	Zoster immunoglobulin

1. Scope

This document outlines the process for accessing immunoglobulin blood products and antitoxin for public health disease control activities in Western Australia (WA) and is intended to guide both medical practitioners and public health staff.

Table 1 summarises the supply and access pathways for the products included in this document, with further details on accessing each product – including WA Health cache stock – provided in the following sections. Medical practitioners should refer only to the first section for each product.

Table 1: Supply and access of immunoglobulin and antitoxin for communicable diseases

Product	Governance of supply	Access for medical practitioners
Human rabies immunoglobulin (HRIg) and **rabies vaccine** for **post-exposure prophylaxis**	Governed by WA Health public health physicians (PHPs) in public health units and the Communicable Disease Control Directorate (CDCD).	Medical practitioners must contact their local public health unit (or the on-call PHP if after hours).
Normal human immunoglobulin (NHIg), **zoster immunoglobulin (ZIg)** and **tetanus immunoglobulin**	Governed by the National Blood Authority and supplied by the Australian Red Cross (Lifeblood) Service.	Medical practitioners: • **NHIg**: must contact their local public health unit (or the on-call PHP if after hours) • **ZIg**: can order via National Blood Authority's BloodNet • **tetanus immunoglobulin**: can order via BloodNet.
Botulinum immunoglobulin (BabyBIG) for **infant botulism** and **botulinum antitoxin (BAT)**	**BabyBIG** is made and distributed by the California Department of Public Health and governed by the Therapeutic Goods Administration (TGA) Special Access Scheme. **BAT** is available through the National Medical Stockpile with pre-positioned stock located in WA.	Medical practitioners must contact CDCD (or the on-call PHP if after hours).
Diphtheria antitoxin (DAT)	Supply is accessed through the TGA Special Access Scheme, with a small quantity pre-positioned in WA.	Medical practitioners must contact CDCD (or the on-call PHP if after hours).

Refer to Resources section for further supporting information as required.

2. Process for accessing and ordering HRIg and rabies vaccine for post-exposure prophylaxis

Possible exposures to rabies and other lyssavirus, including Australian Bat Lyssavirus (ABLV), should be managed in accordance with the Rabies and other Lyssaviruses chapter in the Australian Immunisation Handbook and the CDNA National Guidelines for Public Health Units.

2.1 Actions by the treating medical practitioner

Use of rabies vaccine and HRIg for **post-exposure prophylaxis**, including cache stock, requires approval by public health prior to administration.

If patients have had possible exposure to rabies or other lyssaviruses overseas or within Australia, **health practitioners must contact public health** for advice and approval to access rabies post-exposure prophylaxis, even if the patient attends a site holding cache stock:

- **Monday to Friday 8.00am to 5.00pm:** Call local public health unit
- **After hours:** Call the on-call PHP via **1800 434 122**.

Health practitioners should provide first aid and wound management, as required, and consider tetanus and other infections. Public health will collect relevant information from the health practitioner about the exposure, including:

- patient details (e.g. name, date of birth and address)
- exposure details (e.g. country of exposure, animal, date of incident, description of incident, and severity and location of wound)
- measured patient weight
- if patient has an egg allergy, or is immunocompromised
- if patient has had any rabies vaccine **prior** to the exposure
- date/time and brand of any rabies vaccine or immunoglobulin already given **after** the exposure.

In metropolitan Perth, an online form is used to collect this information and is emailed to the health practitioner on request.

Once public health approval is given, health practitioners at a facility with cache stock can administer the post-exposure prophylaxis immediately. Health practitioners at a facility without cache stock will have stock ordered and delivered to them (urgently if required). Post-exposure prophylaxis should be administered as per the Administration of rabies vaccine and HRIG for post-exposure prophylaxis factsheet and provide the patient with Rabies and lyssavirus information.

2.2 Actions by CDCD/public health physicians

Once the health care practitioner has contacted public health, the public health unit/PHP will assess the exposure, provide advice, authorise use of rabies post-exposure prophylaxis, and complete, or facilitate completion of an exposure form (and in most cases, an order form). The process to access HRIg and/or rabies vaccine differs between cache stock sites and other sites (see below), and Appendix B (metropolitan areas) or Appendix C (regional areas) for a list of sites with cache stock.

CDCD's vaccine management team oversees the process of despatching rabies post-exposure prophylaxis during business hours via Onelink, conducts routine checks of cache stock at each approved facility, and maintains case records.

Step 1: Public health unit or on-call PHP **completes** (or facilitates completion of) **exposure form**

- The public health registrar/physician must approve the use of HRIg and/or rabies vaccine by completing the authorisation section at the bottom of the exposure form.
- The public health unit or on-call PHP sends the completed exposure form to vaccineorders@health.wa.gov.au.
- If after hours, the on-call PHP to also copy the local public health unit into the email to enable follow up and/or further post-exposure prophylaxis to be arranged.

Step 2: Public health unit or on-call PHP **completes order form**

**CDCD PHPs may email Vaccine Orders to replace cache stock; an order form is required for all other doses*

Sites with cache stock	Sites without cache stock
Replacement of cache stock only:* → complete **Initial order** section only: request quantity of cache stock used	Immediate doses only (e.g. subsequent doses not required or site unknown) → complete **Initial order** section only, requesting immediately required doses
Replacement of cache stock **and** subsequent doses at the **same** location: → complete **Initial order** section only: request total doses required (doses used from cache stock **+** subsequent doses needed)	Immediate doses **and** subsequent doses at the **same** location: → complete **Initial order** section only, requesting the total doses required
Replacement of cache stock **and** subsequent doses at a **different** location: → complete **Initial order** section: request quantity of cache stock used for replacement **and Subsequent order** section: request subsequent doses needed at other location	Immediate doses **and** subsequent doses at two **different** locations: → complete **Initial order** section requesting doses required at first location **and Subsequent order** section requesting subsequent doses needed at other location

Step 3: Public health unit or on-call PHP **places order with Onelink**

Order placed AND delivery required outside Onelink office hours*	All other ordering/delivery timeframes
• The on-call PHP sends completed order form to priority@onelink.com.au and vaccineorders@health.wa.gov.au. • The on-call PHP to CC the local public health unit into the email. • The on-call PHP **must** confirm **urgent** orders by also calling (not texting) Onelink on **0459 398 111**.	• The public health unit or on-call PHP sends completed order form to customerservice@onelink.com.au and vaccineorders@health.wa.gov.au. • For orders placed after hours, the on-call PHP to CC the local public health unit into the email. • If **urgent** or requested immediately, call **1800 014 207** to confirm order.

** Onelink office hours: Monday to Friday, 6.30am to 4.00pm (excluding public holidays). Standard (non-urgent) orders placed and processed by Onelink before 4.00pm AWST on a business day will be delivered by close of business (i.e. 5.00pm AWST) the following business day in metropolitan Perth.*

3. Process for accessing and ordering NHIg

In Australia, NHIg is available under the national blood arrangements for two specific purposes:

- public health disease control activities, to treat certain susceptible contacts of measles, rubella, poliomyelitis and hepatitis A, where directed by the public health unit
- the treatment of specified immunodeficiency conditions in patients for whom treatment with intravenous immunoglobulin or subcutaneous immunoglobulin is contraindicated.

The National Blood Authority policy on access, supply, and use of NHIg is available at Normal human immunoglobulin (NHIg) | National Blood Authority.

Lifeblood distributes government-funded hyperimmune immunoglobulin products such as NHIg. Although there is pre-positioned cache stock of NHIg at a few metropolitan and regional hospitals in WA (see **Table 2**), Lifeblood is also able to urgently courier NHIg to other sites.

3.1 Actions by the treating medical practitioner

The use of NHIg for post-exposure prophylaxis in public health disease control activities (e.g. for certain susceptible contacts of measles, rubella, poliomyelitis and hepatitis A) **must** be discussed with public health by the treating medical practitioner.

Non-cache sites

Ordering NHIg can be done in one of two ways, depending on whether the facility is set up to order products from Lifeblood:

1. Most hospitals should be able to order NHIg via BloodNet. This may include the hospital laboratory or pharmacy ordering product on behalf of the treating medical practitioner. The person submitting the order must include a comment noting which public health unit/PHP provided advice to request NHIg for this use.
2. GP clinics and hospitals who are not set up to order products via BloodNet should complete the NHIg order form, and include details about which public health unit/PHP provided advice to request NHIg for this use. The form must be submitted to Lifeblood WA at BloodNetWA@redcrossblood.org.au, with **urgent** requests followed by a phone call to **(08) 9325 3030**.

Medical practitioners can contact the local Lifeblood Customer Service Delivery team to confirm whether their facility is set up to order products from Lifeblood.

Cache sites

Medical practitioners at facilities with jurisdictional approval to hold NHIg stock, must still contact public health for approval to release NHIg from pre-positioned cache stock prior to administration. However, these facilities can place routine orders via BloodNet to replenish cache stock as required, without including a comment about which public health unit/PHP provided advice to request NHIg for this use.

3.2 Actions by CDCD/on-call public health physician

Public health units and PHPs should be contacted regarding the use of NHIg for post-exposure prophylaxis for certain susceptible contacts of measles, rubella, poliomyelitis and hepatitis A, and provide approval that NHIg can be requested for this use, including release from pre-positioned cache stock if applicable. They are expected to provide contact details to the medical practitioner for inclusion on BloodNet or the NHIg order form in case any queries arise.

Public health units/PHPs may also need to direct or assist GP clinics and hospitals that are not set up to order products via BloodNet with completing a NHIg order form. The form must be submitted to Lifeblood WA at BloodNetWA@redcrossblood.org.au, with **urgent** requests followed by a phone call to **(08) 9325 3030**. For cache sites, public health units/PHPs should request that the hospital submit a BloodNet order if replenishment of cache stock is required.

For routine orders, Lifeblood has regular courier runs to most Perth metropolitan hospitals, Monday to Saturday. Otherwise, **urgent** orders can be collected at any time from Lifeblood WA at 290 Wellington Street, Perth WA 6000, and delivered to the site via taxi or courier, at the cost of the provider (or public health unit, where urgent use of NHIg for public health disease control is supported by the PHP). Lifeblood WA supplies the product in a validated transport container, and arrangements must also be made for return of this container via courier once the product has been removed.

Routine deliveries to regional hospitals occur overnight, Monday to Thursday – if a product is needed **urgently** in a regional area or outside routine delivery times, then the regional or on-call pharmacist should be contacted to determine if there is any existing NHIg available in the region that could be used. Otherwise, **urgent** orders are scheduled to arrive as soon as possible depending on the commercial flights available on the day.

Table 2: WA Health-approved facilities for storing NHIg

Hospital or facility	Location and access	Phone number	NHIg 5mL vial	NHIg 2mL vial
Perth Children's Hospital	24 hours a day, 7 days a week Pathwest Transfusion Medicine Laboratory	(08) 6383 4015	Yes	Yes
Broome Regional Hospital Pharmacy	Stock in pharmacy, Mon-Fri 0800-1600 **After hours:** Access available via nurse manager, phone (08) 9194 2630	(08) 9194 2821	Yes	Yes
Southwest Health Campus – Bunbury	Stock in pharmacy, Mon-Fri 0800-1630 **After hours:** Access available via after-hours coordinator and BIONIC team, (08) 9722 1262 or 0439 073 424	(08) 9722 1416	Yes	Yes
Geraldton Regional Hospital Pharmacy	Stock in pharmacy, access Mon-Fri 0800-1600 via Regional Chief Pharmacist Midwest **After hours:** Access available via nurse manager, (08) 9956 2222	(08) 9956 2234	Yes	Yes
Hedland Health Campus	Stock in emergency department (ED) with access for pharmacist, Mon-Fri 0800-1600 **After hours:** Access available via nurse manager, phone (08) 9174 1434	(08) 9174 1334	Yes	Yes
Kununurra Community Health	Stock in ward pharmacy store, Mon-Fri 0800-1600 **After hours:** Access available via hospital reception, (08) 9166 4222	(08) 9166 4321	Yes	Yes

4. Process for accessing and ordering ZIg

Information on the use of ZIg is available at Immunoglobulins | Lifeblood. Where necessary, public health can be contacted by the treating medical practitioner for advice and support on the use of ZIg for post-exposure prophylaxis in public health disease control activities (e.g. for susceptible contacts of chickenpox and shingles); however, it is the responsibility of the treating medical

practitioner to place the order for ZIg. Also see Public health management | Varicella (chickenpox) in the Australian Immunisation Handbook for further information about ZIg. Lifeblood distributes government-funded hyperimmune immunoglobulin products such as ZIg.

4.1 Actions by the treating medical practitioner

Approved Health Providers (AHPs) can order ZIg via the National Blood Authority's online blood ordering and inventory management system, BloodNet. A phone call to Lifeblood is **not** required to confirm ZIg ordered through BloodNet. Medical practitioners should refer to Hyperimmune immunoglobulin products | National Blood Authority for further details.

New users of BloodNet will need to register for a BloodPortal account. If the treating medical practitioner is not sure whether their site is an AHP, they can call Lifeblood WA Customer Service Delivery on **(08) 6390 0101** to confirm this. If the site is not an AHP, then Lifeblood can send through a manual form to complete to order ZIg and retrospectively create a new AHP, as appropriate. PHPs only need their own AHP account if there is an ongoing requirement for direct administration of ZIg to patients.

Once ordered, Lifeblood will package the ZIg ready for pick-up. For routine orders, Lifeblood has regular courier runs to most Perth metropolitan hospitals, Monday to Saturday, with the frequency dependent on the AHP being serviced. Routine deliveries to regional hospitals occur overnight, Monday to Thursday.

If a product is needed **urgently** or outside routine delivery times, or for new AHPs, then Lifeblood will request that the provider arranges product collection at any time from Lifeblood WA at 290 Wellington Street, Perth WA 6000, and delivery to their site via taxi or courier, at the cost of the provider (or public health unit, where urgent use of ZIg for public health disease control is supported by the PHP).

Where ZIg is not approved or unavailable, Lifeblood and the provider will liaise regarding an alternative treatment, and the PHP may be consulted for advice.

5. Process for accessing and ordering tetanus immunoglobulin

Tetanus is a rare but serious illness caused by a toxin produced by the *Clostridium tetani* bacterium. **Intramuscular** tetanus immunoglobulin may be used to manage tetanus-prone wounds in susceptible individuals. See People who have a tetanus-prone wound and Guide to tetanus prophylaxis in wound management in the Australian Immunisation Handbook for further details. **Intravenous** tetanus immunoglobulin is used to treat clinical tetanus.

5.1 Actions by the treating medical practitioner

Tetanus infection is a notifiable infectious disease in WA, and cases must be reported **urgently** by phone to the public health unit (or on-call PHP) within 24 hours of first suspicion of diagnosis. However, the treating medical practitioner should consult with an infectious diseases physician for advice about clinical management of tetanus infection.

Medical practitioners must contact Lifeblood to access tetanus immunoglobulin via the National Blood Authority's online blood ordering and inventory management system, BloodNet. New users of BloodNet will need to register for a BloodPortal account. If the treating medical practitioner is not sure whether their site is an AHP, they can call Lifeblood WA Customer Service Delivery on

(08) 6390 0101 to confirm this. Medical practitioners should refer to Hyperimmune immunoglobulin products | National Blood Authority for further details on ordering tetanus immunoglobulin. Also see Vaccines, dosage and administration | Tetanus in the Australian Immunisation Handbook for further information about tetanus immunoglobulins.

6. Process for accessing and ordering botulism treatment

Botulism is a rare but serious illness associated with descending paralysis, and is caused by a toxin produced by the *Clostridium botulinum* bacterium. It can occur following ingestion of contaminated food, soil or dust, with children under the age of 12 months most at risk of infection. Botulism can also occur from contamination of a wound, generally by infected soil or gravel. Botulism is a notifiable infectious disease in WA, and cases must be reported **urgently** by phone to the public health unit (or on-call PHP) within 24 hours of first suspicion of diagnosis.

If botulism is suspected, an infectious diseases physician should be contacted for clinical advice. Human-derived botulism immunoglobulin (BabyBIG) and equine-derived heptavalent botulinum antitoxin (BAT) can be considered for the treatment of suspected or confirmed botulism in addition to supportive treatment. In infant botulism and other forms of intestinal botulism, antibiotics are generally not used to treat the infection as lysis of intraluminal *Clostridium botulinum* may increase the amount of toxin available for absorption.

BabyBIG is licensed by the United States Food and Drug Administration (US FDA) for the treatment of **infant botulism** caused by *Clostridium botulinum* with serotype A or type B toxins in children less than 12 months of age – see Infant Botulism Treatment and Prevention Program for further information.

BabyBIG is made and distributed by the California Department of Public Health, with the cost of the product estimated at US$45,300 per vial. Each single-use vial contains 100 mg ± 20 mg lyophilised immunoglobulin. The recommended dose is 1.0 mL/kg (50 mg/kg) given as a single intravenous infusion.

BAT is licensed by the US FDA for the treatment of symptomatic foodborne or wound botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F or G in adults and paediatric patients aged 12 months or older. Although the preferred product for the treatment of infant botulism is BabyBIG, BAT can be considered for infants requiring treatment if BabyBIG is unavailable or its delivery is likely to be significantly delayed.

6.1 Actions by the treating medical practitioner/infectious diseases physician

Where an infectious diseases physician identifies, or a public health unit is made aware of, a need for BabyBIG or BAT, they must phone CDCD at the Department of Health on **(08) 9222 2131** during business hours or the on-call PHP via **1800 434 122** if after hours, to facilitate access from overseas (BabyBIG) or the National Medical Stockpile (BAT).

The treating medical practitioner must also ensure informed consent for the proposed treatment has been obtained from the patient or parent/guardian (or their legal representative) and a patient consent form is completed.

BabyBIG

If clinical assessment supports infant botulism, treatment should be commenced as soon as possible (preferably within 72 hours but up to 7 days of hospitalisation), without waiting for

laboratory confirmation. However, BabyBIG needs to be couriered from the California Department of Public Health and is likely to take at least 48 hours to arrive.

A TGA Special Access Scheme Category A Form must also be completed via the online system located at Special Access Scheme Custom Portal. Although the prescriber must be a medical practitioner, a health practitioner (e.g. pharmacist) can submit the form on behalf of the prescriber. If the patient is seriously ill, then BabyBIG may be accessed immediately, and a form submitted to the TGA within 28 days of use – however, where possible, a form should be submitted immediately and a copy of the submission receipt that is sent to the health practitioner's email address (or manually downloaded from the Special Access Scheme dashboard) forwarded to CDCD (or on-call PHP) at doh_cdcdoncall@health.wa.gov.au. The requesting health practitioner must register for an account to access the online system – see Special Access Scheme for further details or contact SAS.Support@health.gov.au for support.

Botulinum antitoxin

If BAT is to be used it should be administered as soon as possible – it is generally not recommended if a patient's exposure is greater than 72 hours before administration (or 7 days for infant botulism). Antitoxin does not reverse paralysis but arrests its progression. Skin testing for sensitivity to antitoxin should be performed before administration. The recommended dosage for an adult is one vial, administered intravenously. The dosage varies with the age of the patient but does not exceed one vial per patient. See BAT (Botulism Antitoxin Heptavalent) | FDA for further prescribing information on this product.

BAT is available through the National Medical Stockpile, with pre-positioned stock located in WA to ensure timely access. Commonwealth Chief Medical Officer approval is required to release stock from the National Medical Stockpile (including pre-positioned stock). Where an infectious diseases physician identifies, or a public health unit is made aware of, a need for BAT, they must phone CDCD at the Department of Health on **(08) 9222 2131** during business hours or the on-call PHP via **1800 434 122** if after hours.

A TGA Special Access Scheme application is not required to access to products supplied through the National Medical Stockpile.

6.2 Actions by CDCD/on-call public health physician

BabyBIG

The Department of Health may need to liaise with the Australian Department of Health and Aged Care to facilitate transition through customs. Also see International Inquiries | Infant Botulism Treatment and Prevention Program for further information about international access of BabyBIG. BabyBIG will then be couriered to the treating medical practitioner (likely to take at least 48 hours).

Botulinum antitoxin

The process for CDCD or the on-call PHP to access BAT is as follows:

1. As pre-positioned stock of BAT is located in WA, the on-call duty officer must be advised of the request via **1800 434 122**. This also ensures that concurrent requests for the same treatment are not being actioned.
2. Confirm with the on-call duty officer the jurisdictional contact person/requestor details to include on the Request to access the National Medical Stockpile form (located in the WA After Hours Communicable Diseases folder on Microsoft Teams).
3. Complete the Request to access the National Medical Stockpile form and seek approval from the Chief Health Officer (or their authorised delegate) to access BAT by emailing them the

completed from to sign and return, with CC to doh_cdcdoncall@health.wa.gov.au and Duty.OnCall@health.wa.gov.au. The State Health Coordinator will need to facilitate approval from the Chief Health Officer if after hours.

4. The on-call duty officer will contact the National Incident Centre 24-hour helpline on **(02) 6289 3030** to advise of the request, and send the completed and signed request form to health.ops@health.gov.au and copy to stockpile.ops@health.gov.au, doh_cdcdoncall@health.wa.gov.au and Duty.OnCall@health.wa.gov.au.
5. The National Incident Centre will contact the National Medical Stockpile on-call officer who will action the request.
6. The National Medical Stockpile on-call officer will call or email the jurisdictional contact person/requestor and arrange for approval from the Commonwealth Chief Medical Officer or authorised delegate.
7. Once approved by the delegate, the National Medical Stockpile on-call officer will advise the jurisdictional contact person/requestor that the request has been approved and will liaise with the warehousing and logistics provider to arrange immediate deployment to the delivery address.
8. Once the BAT has been administered, the jurisdictional contact person/requestor is to advise the National Medical Stockpile of the quantity of pre-positioned stock remaining. The jurisdiction is to also advise the National Medical Stockpile if the BAT was not administered to the patient.

7. Process for accessing and ordering DAT

Diphtheria is a rare disease caused primarily by toxigenic strains of *Corynebacterium diphtheriae* (and less commonly, toxigenic strains of *Corynebacterium ulcerans*) bacteria. There are two main forms – respiratory and cutaneous. Nontoxigenic strains occasionally cause disease of varying severity, particularly in vulnerable populations, but do not meet the definition of diphtheria. Diphtheria is a notifiable infectious disease in WA, and cases must be reported **urgently** by phone to the public health unit (or on-call PHP) within 24 hours of first suspicion of diagnosis.

If diphtheria is suspected, the treating medical practitioner should contact an infectious diseases physician for clinical advice, including the role of DAT. If there is strong suspicion of **respiratory toxigenic** diphtheria, DAT should be given without delay. DAT neutralises circulating toxin and is the mainstay of treatment for respiratory diphtheria, while antibiotics are required to eradicate the organism, stop further toxin production and help prevent transmission. DAT does not reverse symptoms caused by toxin already bound to tissue but limits disease progression, hence making early administration critical. Further information about DAT treatment is outlined in Appendix B of the Queensland Health Guidelines for Public Health Units.

DAT is derived from equine serum. Each 10mL vial contains 10,000 units of diphtheria antitoxin. There is the potential risk of a hypersensitivity reaction ranging from acute anaphylaxis to serum sickness, and sensitivity testing should be considered in accordance with the product information before administering DAT. Adults and children receive the same dose, although the dose depends on clinical severity and should be discussed with an infectious diseases physician. The preferred route is intravenous, particularly in severe cases.

7.1 Actions by the treating medical practitioner/infectious diseases physician

Where the treating medical practitioner, in consultation with an infectious diseases physician identifies a need for DAT, or a public health unit is made aware of a need for DAT, they must phone CDCD at the Department of Health on **(08) 9222 2131** during business hours or the on-call PHP via **1800 434 122** if after hours, to facilitate access to pre-positioned stock in WA or interstate.

Following discussion with public health, a TGA Special Access Scheme Category A Form must be completed via the online Special Access Scheme Custom Portal. Although the prescriber must be a medical practitioner, a health practitioner (e.g. hospital pharmacist) can submit the form on behalf of the prescriber. The submitting health practitioner must register for an account to access the online system – see Special Access Scheme for further details or contact SAS.Support@health.gov.au for support.

A TGA Special Access Scheme Category A Form should be submitted as soon as possible; however, this must not delay urgent release or administration of DAT. Where available, a copy of the submission receipt that is sent to the health practitioner's email address (or manually downloaded from the Special Access Scheme dashboard) should be emailed to the on-call PHP (confirm email address when calling) and CDCD (doh_cdcdoncall@health.wa.gov.au), along with:

- patient UMRN
- brief details about the clinical indication
- approval from the infectious disease physician for DAT and recommended dose
- name, position and contact details of the requesting medical practitioner
- name, position, area, address and contact details of the person receiving the delivery.

These details must be provided to facilitate the release of DAT and should be submitted without delay, even if the SAS form is not yet available.

The treating medical practitioner must also ensure informed consent for the proposed treatment has been obtained from the patient (or their legal representative) and a patient consent form is completed.

The receiving hospital where the patient is admitted is expected to pay for the DAT and associated delivery costs.

7.2 Actions by CDCD/on-call public health physician

DAT needs to be obtained from pre-positioned stock in WA (or from interstate where pre-positioned stock is depleted); it is not held in the National Medical Stockpile.

Kimberley region

To facilitate timely administration of DAT to patients being treated in remote Kimberley locations, a small quantity of DAT is pre-positioned at both Broome Health Campus and Kununurra District Hospital. The process for the CDCD PHP **(business hours)** or on-call PHP **(after hours)** to facilitate access to DAT from the Broome or Kununurra stockpile is as follows:

1. Confirm that an infectious diseases physician has approved the use of DAT and the dose required.
2. Confirm that the treating clinician (or hospital pharmacist) has or will complete the online TGA Special Access Scheme Category A form (located at the Special Access Scheme Custom

Portal), and request that the submission receipt is forwarded to the both the on-call PHP and CDCD (doh_cdcdoncall@health.wa.gov.au).

3. During **business hours**, the Diphtheria antitoxin (DAT) request form should be completed by the PHP and emailed to the relevant hospital pharmacy. **After hours**, the form should also be emailed to the hospital after-hours nurse manager **in addition to pharmacy**. See Table 3 below for Broome and Kununurra contact information. Ensure CDCD is included in the email (cc: doh_cdcdoncall@health.wa.gov.au).
4. The CDCD or on-call PHP should contact the relevant hospital pharmacy **(business hours)** or the after-hours nurse manager via **(after hours)** to arrange release of DAT from pre-positioned stock (see Table 3 below).
5. If the patient is not located at the dispensing hospital, the pharmacist or after-hours nurse manager at the dispensing hospital will need to liaise with the receiving facility on the best way to promptly transport DAT while maintaining cold chain requirements.
6. During **business hours**, the CDCD PHP should advise the Chief Health Officer of the request for DAT. **After hours**, the on-call PHP should notify the on-call duty officer of the request for DAT via **1800 434 122** or mobile, with a follow-up email.
7. Ensure usual handover occurs to CDCD (doh_cdcdoncall@health.wa.gov.au) and Kimberley PHU (WACHSKimberleyCommunicableDiseaseControl@health.wa.gov.au) by next business day.
8. In situations where Kimberley DAT stockpiles are depleted, please follow guidance for **Other WA regions** below.

Table 3: Kimberley region key contact details

	Broome Health Campus	Kununurra District Hospital
Business hours (pharmacy)	broome.pharmacy@health.wa.gov.au (08) 9194 2821	matthew.hannagan@health.wa.gov.au 0477 333 758
After hours (nurse manager)	broome.ahnm@health.wa.gov.au (08) 9194 2222	kdhcnm@health.wa.gov.au (08) 9166 4290
	Please include relevant hospital pharmacy in after-hours email communications.	

Other WA regions

For patients being treated in other regions of WA, DAT is pre-positioned in the Disaster Preparedness and Management Directorate (DPMD) warehouse located in Perth. The process for the CDCD PHP **(business hours)** or on-call PHP **(after hours)** to facilitate access to DAT from the DPMD stockpile is as follows:

1. Confirm that an infectious diseases physician has approved the use of DAT and the dose required.
2. Confirm that the treating clinician (or hospital pharmacist) has or will complete the online TGA Special Access Scheme Category A form (located at the Special Access Scheme Custom Portal), and request that the submission receipt is forwarded to the on-call PHP as well as CDCD (doh_cdcdoncall@health.wa.gov.au).
3. During both **business hours** and **after hours**, the Diphtheria antitoxin (DAT) request form should be completed by the PHP and emailed to the on-call duty officer (duty.oncall@health.wa.gov.au). Ensure CDCD is included in the email (cc: doh_cdcdoncall@health.wa.gov.au).

4. During **business hours** the CDCD PHP will liaise directly with the DPMD duty officer for release and transfer of DAT. **After hours**, the on-call PHP should contact the on-call duty officer to advise of the request for DAT via **1800 434 122** (or directly by mobile). This also ensures that concurrent requests for the same patient are not being actioned.
5. During **business hours**, the CDCD PHP should advise the Chief Health Officer of the request for DAT including brief details about the clinical indication and approval from the infectious disease physician. **After hours**, the on-call duty officer should notify the State Health Coordinator of the request for DAT, including brief details about the clinical indication and approval from the infectious disease physician.
6. The DPMD duty officer **(business hours)** or on-call duty officer **(after hours)** will liaise directly with the receiving contact person listed on the request form to arrange delivery of the DAT.
9. Ensure usual handover occurs to CDCD (doh_cdcdoncall@health.wa.gov.au) and relevant by next business day. CDCD to notify DPMD team by email (duty.oncall@health.wa.gov.au) of confirmed receipt of DAT and any reported issues (e.g. cold chain integrity breaches).

8. Additional resources

Resource	Details
National Blood Authority webpages	• BloodNet for blood products from Lifeblood • Normal human immunoglobulin (NHIg) • Hyperimmune immunoglobulin products
WA Department of Health webpages, including details on notification requirements, overview of public health management, and links to guidelines	• Botulism • Hepatitis A • Measles • Poliovirus infection • Rabies and other lyssaviruses (including ABLV) ○ Rabies vaccine and HRIG administration advice • Rubella • Tetanus • Varicella-zoster (chickenpox and shingles)

Public Health Management sections of Australian Immunisation Handbook pages	• Hepatitis A
	• Measles
	• Rubella
	• Tetanus
	  ○ People who have a tetanus-prone wound
	  ○ Guide to tetanus prophylaxis in wound management
	  ○ Vaccines, dosage and administration
	• Varicella

Communicable Diseases Network Australia (CDNA) Series of National Guidelines (SoNGs) for Public Health Units	• Hepatitis A • Measles • Rabies and other lyssavirus
Public health guidelines from other jurisdictions	• Botulism • Botulism control guideline • Varicella-zoster infection (chickenpox and shingles)

9. Contact details for public health

Contact details for public health units are available at:
https://www.health.wa.gov.au/articles/a_e/contact-details-for-public-health-units.

Appendix A: Rabies virus and other lyssaviruses post-exposure follow-up checklist for public health

For potential exposures to rabies or other lyssavirus (including ABLV)

1. Liaise with the attending medical practitioner or contact the exposed person (or caregiver) to:
    - identify source and circumstances of potential exposure, including the animal involved and the country where the exposure occurred – for exposures to bats, try to identify the type and species
    - determine if any other persons or animals were exposed to the same animal
    - determine if the animal is available for testing and arrange testing, where appropriate (see below)
    - review exposed person's rabies vaccination status and immune competence, and discuss need for post-exposure prophylaxis and if they have a preferred general practitioner or clinic for this
    - request copy of vaccine card for any post-exposure prophylaxis commenced overseas
    - complete, or facilitate completion of, the Rabies and other lyssaviruses: exposure form or online form in metropolitan Perth
    - provide patient with the Rabies and lyssavirus factsheet.

2. Contact exposed person's doctor/clinic to discuss need for wound management and provision of post-exposure prophylaxis, and confirm they are able to complete the course of post-exposure prophylaxis on applicable dates.

3. Arrange post-exposure prophylaxis to nominated provider(s):
    - Cache stock is maintained at selected WA hospitals and facilities – see Appendix B (metropolitan areas) and Appendix C (regional areas) for a list of sites with cache stock.
    - Two forms are completed by the public health unit or on-call public health physician (in liaison with the attending doctor) or by WA Health-approved travel clinic doctors:
        - Rabies and other lyssaviruses: exposure form
            - submitted to vaccineorders@health.wa.gov.au
        - Rabies and other lyssaviruses: order form
            - submitted to customerservice@onelink.com.au
            - copy to vaccineorders@health.wa.gov.au.
    - During office hours, phone Onelink on **1800 014 207** to follow up if no email response within one hour of ordering, or **urgent** delivery is required. After hours, always phone Onelink on **0459 398 111** to confirm the order.
    - The warehouse will confirm receipt of the order and delivery timing to the hospital or facility.
    - The PHP must ensure their contact details are current for any queries that may arise.

Facilitate animal/bat testing, where appropriate

For fruit bat (flying fox) and microbat exposures in WA, wherever possible and without putting others at risk of exposure, the public health unit should arrange for the bat to be sent to the Department of Primary Industries and Regional Development (DPIRD) Diagnostics and Laboratory Services for testing.

Only appropriately vaccinated and trained people should handle bats. If bats must be handled, every effort should be made to avoid being bitten or scratched, including using appropriate personal protective equipment, such as puncture-resistant gloves and gauntlets, long sleeved clothing, safety eyewear or face shield to prevent mucous membrane exposures, and a towel to hold the bat.

Submission of the implicated bat for testing can normally be arranged by emailing DDLS@dpird.wa.gov.au or by calling the DPIRD duty pathologist on **(08) 9368 3351** during business hours (between 8.00am and 4.00pm). Otherwise, field veterinary officers can be contacted between 7.00am and 8.00pm via the Emergency Animal Disease Hotline on **1800 675 888**. For urgent submissions, field veterinary officers can liaise with laboratory staff to have samples processed outside of normal hours, such as on weekends.

The public health unit should bear the costs of transport of the implicated bat(s). All bats **must** be euthanised, preferably through gaseous anaesthesia, prior to transport – neither field veterinary officers or Diagnostics and Laboratory Services staff carry volatile anaesthetic agents, and few staff are vaccinated against rabies and able to handle a live bat. The euthanised bat should be kept at 4°C (not frozen) for transport.

Local trained and vaccinated bat handlers are available through the Wildlife Information, Rescue and Education Service on **1300 094 737**. Additionally, there are specific wildlife veterinary clinics, such as WA Wildlife, that have veterinarians who are vaccinated against rabies and are trained to handle bats. Live bats may be sent to one of these clinics for assessment and euthanasia, if appropriate on animal welfare grounds – DPIRD does not have the authority to order euthanasia of a healthy native animal.

For testing enquiries or to submit animal specimens for testing to DPIRD Diagnostics and Laboratory Services:

1. Email DDLS@dpird.wa.gov.au with details of the submission. Email is preferred, but if necessary, the Diagnostics and Laboratory Services duty pathologist can be contacted on **(08) 9368 3351** during business hours.
2. Diagnostics and Laboratory Services will triage the submission and email through instructions. Only send samples once Diagnostics and Laboratory Services have responded to ensure sample integrity is maintained and testing can be best facilitated.
3. Arrange courier, affix the submission form to the outside of the bat container and label as below.

   URGENT – bat (human exposure)
   Duty Pathologist, DPIRD Diagnostics and Laboratory Services
   Receivals (C Block), Building 102, 3 Baron-Hay Court
   SOUTH PERTH WA 6151
4. Signage at the entrance to the South Perth site will instruct the sample courier how to proceed.
5. See DPIRD Diagnostics and Laboratory Services for further details.

DPIRD Diagnostics and Laboratory Services will forward specimens to the Australian Animal Health Laboratories in Victoria for Australian bat lyssavirus testing.

Commence post-exposure prophylaxis as per recommendations until a reliable negative result is available. In situations determined to be lower risk, commencement of post-exposure prophylaxis can be delayed for 48 hours post-exposure to enable a result from the bat to be received. In situations determined to be higher risk, or if results are not likely to be available within 48 hours of exposure, then post-exposure prophylaxis should be commenced. If the bat tests negative, post-exposure prophylaxis is not required, and may be discontinued if already commenced.

Testing of animals implicated in exposures will rarely be feasible or undertaken in developing countries; however, if there is information that animal testing has been undertaken, results should be sought from the appropriate authorities.

Appendix B: WA Health-approved facilities for storing HRIg and rabies vaccine: metropolitan area

Cache stock site	Address for replacement of cache stock	Contact details (and after hours access)	Level of cache stock		Location of cache stock
			Verorab vials	2ml HRIg vials	
Central City Medical Centre	Shop 14/378 Wellington Street, Perth WA 6000	Practice manager, 0422 511 906 **After hours:** Practice manager, 0422 511 906	4	12	Vaccine fridge in staff room with government-funded vaccines (separate to travel vaccines)
Fiona Stanley Hospital ED	Lower Ground Floor, 102-118 Murdoch Drive Murdoch WA 6150	Associate nurse unit manager, (08) 6152 7632 **After hours:** Nursing coordinator, (08) 6152 7643	8	20	Green area fridge near medication station
Illawarra Medical Centre* (Mon–Fri 0830-1700)	Ballajura City Shopping Centre 229 Illawarra Crescent South Ballajura WA 6066	Phone: (08) 9208 6400 **No after-hours access** Rabies vaccine for all ages, but HRIg for adults only	3	8	Vaccine fridge in treatment room
Joondalup Health Campus ED (HPS Pharmacies Lakeside)	Ground Floor, Medical Centre West 60 Shenton Avenue Joondalup WA 6027	Mon/Fri: Pharmacy purchasing officer, (08) 9400 9377 Tues–Thurs: ED clinical nurse specialist, (08) 9400 9002 **After hours:** ED shift coordinator, (08) 9400 5253 or (08) 9400 6468	3	8	Imprest room fridge in D pod area within ED
Perth Children's Hospital ED	Pharmacy Department Winthrop Avenue, Enter Via Nedlands WA 6009	Supervisor pharmacist clinical services, (08) 6456 0190 **After hours:** ED shift coordinator via switchboard (08) 6456 2222	3	8	ED pod C fridge attached to automated dispensing machine
Royal Perth Hospital ED	ED Nurse Practitioner on Duty Royal Perth Hospital ED Triage Victoria Square Perth WA 6000	ED nurse practitioner, (08) 9224 2130 **After hours:** ED nurse practitioner, (08) 9224 2130 or ED shift coordinator via switchboard (08) 9224 2244	3	8	RADA fridge located underneath bench in treatment area, next to cubicle 4
Sir Charles Gairdner Hospital Pharmacy	Rear of Block A, Receivals Ramp Verdun Street Nedlands WA 6009	ED pharmacy, (08) 6457 6731 **After hours:** ED shift coordinator via switchboard (08) 6457 3333	3	8	Fridge in assessment imprest room
Travel Medicine Centre/Mill St Medical Practice* (Mon-Thurs 0800-1700, Fri 0800-1600, Sat 0830-1230)	Ground Floor, 200 St George's Terrace Perth WA 6000	Phone: (08) 9321 7888 **No after-hours access**	9	14	Vaccine fridge

* Private billing for first appointment then bulk billing/nurse fee only for subsequent visits.

Appendix C: WA Health-approved facilities for storing HRIg and rabies vaccine: regional areas

Cache stock site	Address for replacement of cache stock	Contact details (and after-hours access)	Level of cache stock		Location of cache stock
			Verorab vials	2ml HRIg vials	
Albany Health Campus Pharmacy	Hardie Road Albany WA 6330	Regional chief pharmacist, 0428 624 713 or (08) 9892 2272 **After hours:** Nurse manager (has access to pharmacy), (08) 9892 8224 or 0448 726 204	4	8	Fridge 6 on left-hand side of pharmacy safe – basket with stock and paperwork on left-hand side of second shelf from top
Broome Regional Hospital Pharmacy	Walcott Street Broome WA 6725	Pharmacy assistant, (08) 9194 2821 **After hours:** Shift coordinator (08) 9194 2678	8	12	Pharmacy Z1 fridge – third shelf on left-hand side
Geraldton Regional Hospital Pharmacy	51-85 Shenton Street Geraldton WA 6530	Regional chief pharmacist Midwest, (08) 9956 2234 **After hours:** Nurse manager, (08) 9956 1837	4	8	Fridge number 3 and 4 in pharmacy
Hedland Health Campus Pharmacy	Colebatch Way South Hedland WA 6722	Regional chief pharmacist, (08) 9174 1334 **After hours:** After-hours nurse manager 0467 777 439 or regional chief pharmacist 0447 732 211	4	8	Fridge in ED – bottom shelf on right-hand side in a wire basket
Kalgoorlie Health Campus Pharmacy	Piccadilly Street Kalgoorlie WA 6430	Pharmacy technician, (08) 9080 5655 **After hours and weekends:** A/Health system support officer, 0427 087 147	4	8	Vaccine fridge number 4
Karratha Health Campus Pharmacy	62 Balmoral Road Karratha WA 6714	Senior pharmacy technician, (08) 9144 7766 **After hours:** After-hours nurse manager, (08) 9144 7502	4	8	Fridge in ED medication room
Kununurra Hospital – Pharmacy Department	96 Coolibah Drive Kununurra WA 6743	Senior regional clinical pharmacist, 0477 333 758 **After hours:** After-hours nurse manager, (08) 9166 4290	4	6	Pharmacy fridge
Southwest Health Campus Bunbury – Pharmacy Department	Corner Bussell Highway and Robertson Drive Bunbury WA 6230	Pharmacy technician, (08) 9722 1416 **After hours:** After-hours coordinator, (08) 9722 1262	8	14	Pharmacy fridge

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