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**Announcement statement**—may be announced to the public.

**Secondary release**—may be released to the Australian Government Department of Defence, its contractors and their equivalents in United States of America, Canada, New Zealand and Great Britain


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**Health Manual, volume 5**

First edition 2014

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**Sponsor**

Director General Strategic Health Coordination

**Developer**

Directorate Military Medicine

**Publisher**

Defence Publishing Service
Department of Defence
CANBERRA ACT 2600
IMMUNISATION

Health Manual (HLTHMAN), volume 5, —Immunisation is issued for use by all Defence agencies and is effective forthwith. This publication supersedes Australian Defence Force Publication (ADFP) 1.2.21—Immunisation Procedures, all copies of which should be destroyed.

R.M.WALKER, AM
Rear Admiral, RAN
Surgeon General Australian Defence Force

Department of Defence
CANBERRA ACT 2600
30 January 2014
FOREWORD

1. Surgeon General Australian Defence Force (SGADF) has responsibility for technical control of the Australian Defence Force (ADF) Health Services, that is, all personnel involved in the provision of health care (which includes psychology services) within the ADF. Additionally, SGADF is responsible for the provision of specialist advice, development of policy on health issues, delivery of all garrison health care, and is the lead health capability coordinator for health materiel.

2. Technical control is the specialist or professional guidance and direction exercised by an authority in technical (professional) matters. Technical control is not a command or operational authority but may be used where necessary to designate the specialised and professional operating procedures essential to the proper management of the health of forces. SGADF exercises technical control of the ADF health services through the development and promulgation of policy and advice.

3. Health policy that has general application to the administration of the ADF, and not just to the Health Services, is promulgated in the form of either Defence Instruction (General) or Australian Defence Doctrine Publications.

4. In accordance with Defence Force Regulations 1952 (http://www.comlaw.gov.au/Details/F2013C00429) 58F(1) the Commonwealth must provide medical and dental treatment required to keep Defence members healthy for the purpose of discharging their duties; subject to subregulation (2), which gives the Minister the power to make a determination in relation to the provision of treatment, taking into account:
   a. the treatment facilities available;
   b. the duties of the member; and
   c. the operational requirements of the ADF.

5. The Australian Defence Force Publication (ADFP) 1.2.2 — Casualty Prevention (http://intranet.defence.gov.au/home/documents/adfdocs/ADFP/adfp1_2_2.htm) states:
   a. During operations, providing a fit and healthy force becomes an enabler to support the primary tasks of preventing and treating casualties. Casualty prevention influences the determinants of health, aiming to promote health and prevent the development of adverse health conditions. The focus of casualty prevention is on both populations and individuals. On the other hand, casualty treatment manages personnel with health conditions, aiming to minimise adverse health outcomes.

Amendment process

6. Proposed technical health policy revisions or changes to Health Manual, volume 5 will be developed and staffed through the Defence Health Policy Working Group and the Defence Health Policy Steering Group and approved by the single Service health stakeholders.
7. This first edition of Health Manual, volume 5 is a limited update of the content from ADFP 1.2.2.1—Immunisation Procedures dated September 2004. Other than editorial changes, the content of chapter 5 Vaccinations against biological warfare agents and chapter 8 Antivenoms has not been updated at this time. The content of chapter 6 has been deleted. Chapter 6 is reserved for immunisation data in electronic health records. The remaining content has been updated to reflect current terminology and vaccines in use, current clinical and administrative practice and current contact details for external organisations and programs. Future updates will be incorporated on an ongoing basis.

8. ADFP 1.2.2.1, Health Bulletin (HB) 07/2000 Use of multi-dose vials within the Defence Health Service, HB 05/2010 Human papillomavirus vaccination in the Australian Defence Force and HB 03/2012 Immunisation against Japanese encephalitis in the Australian Defence Force will be cancelled on release of this manual.
AMENDMENT CERTIFICATE

Proposals for amendment of HLTHMAN, volume 5 are to be forwarded to:
Director Military Medicine
CP3–6–009
Department of Defence
CANBERRA ACT 2600

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CHAPTER 1
SERVICE VACCINATIONS

Introduction

1.1 The aim of vaccination in the Australian Defence Force (ADF) is to protect the health and enhance the overall effectiveness of Defence members. Vaccination helps to prevent the spread of diseases. Completion of or currency in vaccination schedules is necessary to ensure the preparedness of individuals and units for operational service.

1.2 The vaccination requirements specified in this manual apply to:

a. Defence members in Australia and overseas,

b. dependants of Defence members proceeding outside Australia at Commonwealth expense, and

c. authorised civilians proceeding outside Australia at Commonwealth expense.

1.3 The term ‘Defence health personnel’ for the purpose of this publication includes all military and civilian medical officers, registered nurses, medical assistants and enrolled nurses employed or contracted to work in Defence health facilities. It must be noted that the legislation in some states does not allow enrolled nurses to vaccinate.

1.4 The word ‘vaccination’ is used in the broadest sense as adopted by the World Health Organization (WHO). It covers all procedures known as ‘immunisation’, ‘inoculation’ and ‘vaccination’ and is essentially interchangeable with immunisation. The following definitions apply:

a. immunisation—process of inducing immunity artificially by administering an immunobiological product;

b. active immunisation—induction of immunity, including antibody or antitoxin and cellular immune responses, by the administration of a vaccine or toxoid; and

c. passive immunisation—induction of temporary immunity by preformed antitoxin or antibodies, (for example, immunoglobulin or maternal antibodies).

1.5 A member must give consent prior to receiving any vaccination. Members are to be given information on the risks and benefits of vaccination so that they can make an informed decision. Written consent is required for unregistered vaccines. Chapter 3—‘Standard vaccination procedures’ and Chapter 5—‘Vaccinations against biological warfare agents’ refer. Failure to consent to vaccinations may lead to members being deemed non-deployable and may lead to a review of their fitness to continue serving in the ADF. Failure to consent to vaccinations required for a specific deployment may lead to the member being deemed ineligible for that deployment. Chapter 2—‘Administrative management’ refers.
1.6 As vaccines vary in efficacy, no vaccine is guaranteed to result in immunity in every individual. However, with few exceptions, the efficacy of vaccines is sufficiently high that testing for confirmation of immunity is not required. In some cases, for example, anthrax vaccine, there is no reliable method of testing for vaccine-induced immunity.

1.7 There is a lag time between the administration of vaccine and the development of immunity. In the case of vaccinations with a single dose primary schedule, for instance, immunity develops after ten to fourteen days. For some vaccines, such as hepatitis A, immunity occurs before completion of the primary schedule, but is not long-lasting. Lag times should be taken into account in determining vaccination programs.

1.8 For some vaccines, for example, Hepatitis A and B, lifetime immunity is provided by the primary schedule. Others require a periodic booster (eg diphtheria) or re-vaccination (eg typhoid) in order to maintain immunity (Table 4-3).

Routine and additional vaccinations

1.9 Defence members are required to be immunised against several diseases; the routine vaccinations (Table 4-1). The majority of these vaccinations are included in the Australian standard vaccination schedule (ASVS). Recruits may not need additional doses of these on entry, provided they have adequate documentation of prior doses. Other vaccines, such as Hepatitis A and Typhoid, are not part of the ASVS, and will usually need to be given on entry.

1.10 In addition to the routine vaccinations, Defence members may require additional vaccinations (Table 4-2). These vaccinations provide protection against diseases considered a risk for operational deployments, including biological weapons, or to which some personnel may be particularly susceptible. Defence members may require protection against diseases for which no vaccine is registered in Australia. Chapter 5 refers to the use of unregistered vaccines.

Publications


1.12 The schedules in this manual have been designed to meet the operational health needs of the ADF, and there may be differences between the schedules in this manual and the Handbook. Any such differences will be noted in the text. However, there may also be conflict between schedules in this manual and the Handbook owing to revision of the latter. Where a significant conflict is noted, Defence health personnel are to contact the Director of Military Medicine, through their chain of command, for advice.
1.13 To supplement this manual and the Handbook, the WHO publication: International Travel and Health provides information on vaccination recommendations for international travel.

1.14 The publications are obtainable as follows:

   
   (1) Hard copies may be obtained by telephoning 1800 671 811 or through the Immunise Australia website.
   

b. **World Health Organization.** International Travel and Health. Updated annually:
   
   (1) The current version is available the World Health Organization website (http://www.who.int/ith/en/).
   
   (2) The current version is also available in hard copy from WHO and various suppliers in Australia.

**Communicable disease websites**

1.15 For Defence health personnel who need to obtain information on disease outbreaks occurring both within Australia and internationally, these sites have been used to supplement information in this publication:

- [Centers for Disease Control and Prevention](http://www.cdc.gov/)
- [World Health Organization](http://www.who.int/)
- [Communicable Disease Intelligence](http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-cdi-cdiintro.htm)
- [International Society for Travel Medicine](http://www.istm.org/)
CHAPTER 2
ADMINISTRATIVE MANAGEMENT

Introduction

2.1 This chapter describes the administration of vaccinations in the Australian Defence Force (ADF), inclusive of:

a. ADF requirements; and

b. World Health Organization (WHO) regulations for international travellers.

2.2 To be medically fit for deployment, a Defence member must:

a. be classified medically fit for deployment in accordance with the relevant medical classification system; and

b. be current with all routine and additional vaccinations in accordance with the requirements set out in this manual (Table 4-1 and Table 4-2 refer).

2.3 When a member presents for Periodic Health Examination or other formal health assessment or review, the member’s vaccination status is assessed and, upon the medical officer’s (MO) instruction and member’s consent, any required vaccines are given by authorised Defence health personnel.

Vaccination requirement

2.4 Defence Instruction (General) (DI(G)) PERS 36–2—Australian Defence Force policy on individual readiness (http://intranet.defence.gov.au/home/documents/DATA/ADFPUBS/DIG/GP36_02.PDF) requires that members be current for all routine vaccinations to meet the medical component of individual readiness.

2.5 Additionally, the Health Support Plan for a particular operation will identify specific vaccination or prophylaxis requirements in order for the member to be considered fit for deployment on that operation.

Work health and safety requirements

2.6 Vaccines may be classified as a hazardous chemical and/or dangerous good as indicated on the label or in the manufacturer’s safety data sheet. All vaccines which are classified as a hazardous chemical and/or dangerous good must be registered in ChemAlert and procured, stored and administered in accordance with the Defence Hazardous Chemicals Management Program.

Responsibility of medical officers

2.7 Vaccines, antitoxins and immunoglobulins are all prescription medicines. As such they are subject to the regulatory requirements for the control of restricted drugs. Persons other than a medical officer (MO) may be authorised to administer vaccines. However, such administration is only to be undertaken on the authority of a MO as the responsibility for patient safety lies with the authorising MO.
2.8 MO are responsible for:

a. advising commanding officers (CO) on all matters affecting immunisation policy and procedures;

b. authorising and supervising the giving of vaccinations by appropriately trained personnel as necessary;


d. providing statistical and any other reports as required by higher authorities; and

e. reporting any member refusing vaccination to the member’s CO.

Responsibility of Nursing Officers/Advanced Medical Assistants (Advanced Medics)

2.9 Nursing Officers (NO)/Advanced Medical Assistants (Advanced Medics) are responsible to the MO for:

a. supervising personnel under their command who will be administering vaccinations;

b. ensuring vaccinations are correctly administered and accurately recorded;

c. ensuring that the member to be vaccinated is provided with appropriate information about the risks and benefits of vaccination and the risks of vaccine-preventable disease in accordance with the guidelines outlined in Australian Immunisation Handbook (the Handbook) (http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home) and chapter 3, annex B;

d. performing a pre-vaccination assessment to establish that there are no medical conditions that contraindicate vaccination and obtaining consent from the member to be vaccinated (chapter 3, annex A);

e. discussing with the MO any suspected contraindications to vaccination and documenting this; and

f. ensuring that resuscitation equipment is available whenever vaccinations are administered.

2.10 At the end of any vaccination session, a list of all members who have received vaccines is to be signed by both NO and MO. This list will be kept on file within the health facility.
Vaccination regimens

2.11 The supporting health facility is responsible for generating individual vaccination regimens for Defence members after their entry into the ADF. Depending on the member’s vaccination history, administration of routine vaccination primary schedules may take up to six months. It is therefore likely that the vaccination regimen may extend beyond the ab initio or initial training period. Attempts should not be made to shorten vaccination schedules for administrative convenience. This is medically unsound and can lead to both unnecessary adverse events and ineffective vaccination.

2.12 Persons entering the ADF must provide suitable evidence of previous vaccination in order to avoid unnecessary vaccine doses. This evidence will usually apply to vaccines on the Australian standard vaccination schedule (ASVS), but may also apply to other vaccines. Suitable documentation may include an International Certificate of Vaccination (ICV), an infant or school vaccination record, letters from medical practitioners or clinics or records from previous military service. The MO is to exercise judgment on the validity of documentation and other evidence provided. The MO may, at their discretion, deem that a person has had vaccine doses on the basis of verbal evidence alone. These vaccine doses are to be documented in accordance with paragraph 2.20 and paragraph 2.21, signed by the MO, with a clear indication that the doses are deemed to have occurred.

2.13 As soon as practicable after entry, Defence members are to complete primary schedules for the routine vaccines in accordance with Table 4-1, unless the evidence that they have already completed primary schedules has been accepted. If primary schedules have been completed, personnel need only be vaccinated in accordance with the ‘Doses after primary schedule’ column.

2.14 Where an individual provides evidence of a partially complete primary schedule, the schedule is not to be started again, regardless of the interval since previous doses. Rather, the aim is to build on documented doses so that the total number of required doses is given. If no documentation of previous doses is available, the total number of primary schedule doses is to be given. The ‘Primary schedule dose requirements’ and ‘Comments’ columns of Table 4-1 provide guidance on catch-up regimens.

2.15 When preparing individual vaccination regimens, either upon entry or thereafter, MOs are to take into account that:

a. inactivated vaccines can be administered simultaneously on the same day in different sites;

b. administration of live virus vaccines concurrently does not impair immune response or increase rates of adverse events; and

c. live vaccines are either administered at the same time or separated by one month. Table 2-1 lists the live vaccines.
Table 2-1: Live Vaccines

LIVE ATTENUATED VIRUS VACCINES

- Oral typhoid vaccine

OTHER LIVE VACCINES

Duration of immunity following vaccination

2.16 For some vaccines, the completed primary schedule provides lifetime immunity. For others, the primary schedule provides immunity for a defined period. The primary schedule should never be repeated once it has been completed. If protection is required at any future time, only the booster dose should be given. The types of vaccine schedule and periods of immunity conferred are listed in Table 2-2.

Table 2-2: Duration of protection from completed primary schedule or booster dose

<table>
<thead>
<tr>
<th>Vaccine schedule type</th>
<th>Vaccine</th>
<th>Duration of protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary schedule gives enduring immunity</td>
<td>23-valent pneumococcal polysaccharide (23vPPV) (a)</td>
<td>Life</td>
</tr>
<tr>
<td></td>
<td>Combined adult hepatitis A and B</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inactivated poliomyelitis vaccine (IPV) (b)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Measles-mumps-rubella (MMR)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Meningococcal C conjugate (MenCCV)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monovalent hepatitis A</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monovalent hepatitis B</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Varicella-zoster (VZV)</td>
<td></td>
</tr>
<tr>
<td>Vaccine schedule type</td>
<td>Vaccine</td>
<td>Duration of protection</td>
</tr>
<tr>
<td>-----------------------</td>
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<td>------------------------</td>
</tr>
<tr>
<td>Primary schedule gives immunity for a defined period. Further doses are required to continue immunity after this period.</td>
<td>4-valent meningococcal conjugate vaccine</td>
<td>5 years</td>
</tr>
<tr>
<td></td>
<td>Adult diphtheria-tetanus (dT)&lt;sup&gt;c&lt;/sup&gt;</td>
<td>10 years</td>
</tr>
<tr>
<td></td>
<td>Adult diphtheria-tetanus-pertussis (dTpa)&lt;sup&gt;c&lt;/sup&gt;</td>
<td>10 years</td>
</tr>
<tr>
<td></td>
<td>Anthrax vaccine (UK)</td>
<td>1 year</td>
</tr>
<tr>
<td></td>
<td>Anthrax vaccine (USA)</td>
<td>1 year</td>
</tr>
<tr>
<td></td>
<td>Japanese encephalitis (Imojev)</td>
<td>At least 5 years&lt;sup&gt;d&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Japanese encephalitis (JEspect)</td>
<td>At least 3 years after booster dose&lt;sup&gt;e&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Oral cholera (Dukoral)</td>
<td>2 years&lt;sup&gt;f&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Plague</td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td>Rabies</td>
<td>2 years&lt;sup&gt;g&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Smallpox</td>
<td>5 years</td>
</tr>
<tr>
<td></td>
<td>Typhoid</td>
<td>3 years</td>
</tr>
<tr>
<td></td>
<td>Yellow Fever</td>
<td>10 years</td>
</tr>
</tbody>
</table>

**Notes**


(b) In the general community, the primary course of IPV is considered to provide lifelong immunity. For those travelling to polio endemic areas, a booster is required if the last dose of IPV was more than 10 years prior.

(c) The preferred vaccine is dTpa because of waning immunity to pertussis and diphtheria and the risk of exposure to these diseases, as well as tetanus prone wounds, in the deployed setting. Ten yearly dTpa is recommended in Europe and the United States of America, and is given routinely in the US military. Routine 10 yearly boosting is not yet recommended for the general Australian community.

(d) Duration of protection and booster requirement not yet known. Clinical studies to date demonstrate protective antibody levels for at least five years. A booster dose is not recommended at this time.

(e) Single dose booster required for those at ongoing risk of JE and primary course was more than 12 months prior. Longer term booster requirements not yet known. Modelling suggests protection lasts up to 3.8 years after the single booster dose.
(f) For adults. Boosting requires repeat primary course. See the Handbook for details.

(g) Post exposure prophylaxis still required.

Vaccination waiver

2.17 A Defence member who suffers a serious or unexpected adverse event following a vaccine is to be reviewed by an MO prior to receiving any further doses of the same vaccine. Minor adverse events do not contraindicate further vaccination. If completion of a primary schedule or receipt of further doses of a vaccine which requires periodical boosting is medically contraindicated, the member should have their Medical Employment Classification reviewed in consultation with the Senior Health Advisor for their Service. An investigation of alternatives may be sought at this review. Candidates for entry into the ADF who reveal that they are unable to tolerate any of the vaccines likely to be required during service, will have that application refused in accordance with fitness protocols set out in Health Manual, volume 1—Health standards and procedures for entry and transfer (http://intranet.defence.gov.au/home/documents/adfdocs/hlthman/hlthmanv1.htm).

Defence members refusing vaccination

2.18 Members are to be briefed on the risks and benefits associated with all vaccinations and are at liberty to refuse any vaccine. Defence health personnel are not to forcibly vaccinate any individual who refuses a vaccine. However, any member who is not current with routine or any required additional vaccinations (Table 4-1 and Table 4-2) is not compliant with individual readiness policy as defined in DI(G) PERS 36–2 and therefore is unfit to deploy.

2.19 Members who refuse vaccinations are to have that refusal documented in their Unit Medical Record (UMR) and be reported to their CO. New entrants who refuse to receive vaccinations are to have their continued service in the ADF reviewed by the CO of their ab initio training unit.

Vaccination records and recall system

2.20 Defence health personnel are to record vaccinations given as follows:

a. in the member’s Web Form PM 135—International Certificate of Vaccination or Prophylaxis (http://intranet.defence.gov.au/webforms/form?pm135);

b. on a consent form (for unregistered vaccines only); and

c. in the member’s health record.

2.21 Vaccination details recorded in the International Certificate of Vaccination (ICV) must include the type (oral or injectable), brand name of the vaccine, the date and the signature of the person administering the vaccine. Vaccination records in the member’s health record are to include the same details with the addition of the preferred generic term for the vaccine (for example, ‘Hepatitis A vaccine’ as well as ‘Avaxim’), the batch number, the route and the site of administration.

2.22 Other vaccination records the member may possess, such as childhood records, letters, from medical practitioners etc should be incorporated into the ICV.
Where previous records are too bulky to be incorporated in the ICV, certified copies of reduced size are to be taken and placed in the ICV, with original documentation placed in the member’s UMR. This is to ensure that no records are lost, and gaining units can see the full vaccination history of the member.

Entries on Form PM 135—International Certificate of Vaccination or Prophylaxis

2.23 Date entries will be recorded in the following sequence: day, month, and year. The month should be written in full or abbreviated in letters (for example, 5 January 1968 or 5 Jan 68).

2.24 Since the International Health Regulations 2005 came into force in 2007, yellow fever vaccination has had specific recording requirements. The Form PM 135 has been amended to incorporate these. For members with the older style ICV, Form PM 135–1—Yellow fever certificate of vaccination (http://intranet.defence.gov.au/webforms/form?pm135-1) can be completed and secured in the ICV.

2.25 The following information must be recorded for Yellow Fever vaccination:

a. the signature of the approved yellow fever vaccination provider, and their professional qualifications (a NO may carry out the vaccination under the direct supervision of an approved provider);

b. the name of the manufacturer of the vaccine;

c. the batch number of the vaccine;

d. the approved stamp of the authorised vaccination centre, issued by the Commonwealth Department of Health and Ageing; and

e. the signature of the person vaccinated.

2.26 Any amendment of the yellow fever entry in the ICV, erasure or failure to complete any part of it, may render it invalid at the time of review by foreign health authorities.

2.27 All other vaccinations administered to a Defence member are to be entered by health personnel in the appropriate section of the ICV. There are no international requirements for completion of these sections, however it is recommended that the format provided be used. The signature of the MO is not required. The individual administering the vaccine should certify the ICV.

2.28 When the number of spaces allocated to a particular form of vaccination is full, a new ICV is to be issued for subsequent entries. The old certificate is to be retained and attached to the new book. Entries are not to be transferred from the old ICV to the new. The ‘Other Vaccinations’ pages of the ICV are not to be used to record yellow fever vaccinations. The yellow fever vaccination entry is invalid if it is recorded on other than the appropriate page.

Custody of International Certificate of Vaccination

2.29 The custody of ICV for Defence members and their dependants is as follows:
a. **Defence members.** The ICV will normally be kept with the member’s UMR. Members who are posted overseas, travel overseas frequently, or are likely to travel overseas at short notice, can retain their ICV.

b. **Dependants.** Members should ensure the safekeeping of the ICV of all their dependants.

2.30 Members who are being discharged from the Services are to be given their ICV when they complete their final clearances from health facilities. The ICV is not to be archived with the member’s UMR.

**Lost vaccination records**

2.31 If a Defence member’s ICV and UMR have been lost, and there is no documentation held by pharmacy or at a health facility where the member attended vaccination parades, it may be a reasonable assumption that the routine vaccinations have been given. In such cases, the MO can make a case by case assessment. Serological confirmation of immunity may be possible for some diseases.

**Replacement of lost International Certificate of Vaccination**

2.32 An ICV that is lost, inadvertently destroyed, or damaged sufficiently to render the entries illegible, may be replaced by a new one. Records of previous vaccinations will be accepted in lieu of the ICV entries for Service purposes only. Re-vaccination for yellow fever may be necessary if a new ICV is required for overseas travel and cannot be reconstructed.

2.33 For yellow fever vaccination, entries are not to be re-created from other records such as a vaccination register, UMR or computer printout unless:

a. the MO who carried out each previous vaccination is available to sign the form; and

b. the MO has sufficient information to enter the name of the vaccine manufacturer, batch number and exact date of each vaccination.
CHAPTER 3

STANDARD VACCINATION PROCEDURES

Introduction


3.2 Different vaccines must not be mixed in the same syringe. When two or more vaccines are given to a member on the same day they should be injected at different sites and be separated by at least 25 mm using different syringes and needles.

Vaccines in multi dose vials

3.3 The use of multi-dose vials is a recognised risk factor in the transmission of blood-borne infectious diseases in the health care setting. While multi-dose vials are not routinely used in Australia, their use may be required in some circumstances. These include where rapid delivery of vaccine to large numbers of people is necessary, eg during a pandemic, or where no other formulation exists (eg bacille Calmette-Guérin (BCG) vaccine).

3.4 Where there is no alternative and a multi-dose vial must be used, strict infection control procedures are to be followed, in accordance with the Handbook and the Australian guidelines for the prevention and control of infection in healthcare (http://www.nhmrc.gov.au/guidelines/publications/cd33).

3.5 In particular, it is imperative that:

a. a new sterile needle and syringe is used to draw up the required dose from the vial or ampoule on every occasion. A syringe or needle that has already been used to inject an individual must never come into contact with the vial;

b. a new sterile disposable syringe and needle are used for each injection; and

c. the product is discarded if sterility is compromised or questionable.

3.6 The practice of injecting multiple doses of agent to multiple individuals from a single syringe, with only needle changes between each administration, is never to occur.

3.7 Prior to vaccine administration, Defence health personnel are to ensure that:

a. pre-vaccination checklists and consent forms (if required) are completed;

b. appropriate prescriptions, signed by a medical practitioner, are completed. As an alternative to Form PM 120—Prescription (http://intranet.defence.gov.au/webforms/form?pm120), Web Form PM 105—Outpatient Clinical Record
c. routine identification of vaccines is carried out by two Defence health personnel (one of whom must be either a Registered Nurse or a MO) prior to vaccination;

d. all vaccines are refrigerated, monitored and maintained according to current manufacturer/supplier recommendations;

e. each individual dose is checked to see that the expiry date has not lapsed, and that there is no particulate matter or colour change in the vaccine; and

f. the resuscitation equipment, drugs and protocol necessary for the management of anaphylaxis are available.

3.8 Where Defence health personnel are required to vaccinate large numbers, such as at recruit training units, individual prescriptions for each member being vaccinated are not required. The following protocol is to be followed in these instances:

a. the senior medical officer (SMO) supporting a health facility or unit is to maintain ultimate responsibility for administering the vaccinations and is to give written approval for the mass vaccination to occur;

b. the Officer-in-Charge of the pharmacy is to order and issue all the required vaccines on the authority of the SMO;

c. the SMO is to authorise a Nursing Officers (NO) or Advanced Medic to be in charge of providing vaccine information, administration and recording of the vaccinations;

d. all other normal requirements for administering vaccinations as outlined in this manual are to be followed;

e. after the vaccination parade, the NO/Advanced Medic is to complete a nominal roll detailing which vaccines were administered to each member, and the MO is to sign this document. The roll will be returned to the pharmacist along with any surplus vaccines; and

f. where possible the pharmacist is to record the details of the vaccines administered on the member’s individual history in the computer dispensing system. While this is not a record of individual dispensing, it may be a source of reconstruction if an International Certificate of Vaccination (ICV) is lost.

3.9 Vaccinating is not normally an emergency procedure; therefore there is no requirement for a Medic or NO to administer any vaccination without prior approval by a MO.

Approved Product Information

3.10 Personnel authorising and administering vaccines must be familiar with the vaccine Product Information, which has been approved by the Therapeutic Goods
Medical fitness for vaccination

3.11 Prior to any vaccines being administered, a pre-vaccination assessment, to determine medical fitness for vaccination, must be undertaken. Guidelines for this assessment can be found in annex A, Web Form PM 573—Vaccination Checklist (http://intranet.defence.gov.au/webforms/form?pm573) and the Handbook.

Conditions that may preclude vaccination

3.12 Members who have had an anaphylactic reaction to a vaccine should not receive that vaccine again. If a member has had an anaphylactic reaction to a particular component of a vaccine, they should not receive any vaccine containing that component again. The Handbook lists components for vaccines in the Australian standard vaccination schedule (ASVS). The Product Information contains details of components for other vaccines.

3.13 Live parenteral vaccines (Table 2-1), if not administered simultaneously, should be given at least four weeks apart.

3.14 The tuberculin skin test (TST) may be unreliable for four weeks after administration of live vaccines. This is because the reaction to purified protein derivative (PPD), used in the TST, may be suppressed. Therefore, if a member is to have a TST and a live vaccine, the TST should be completed before administration of the live vaccine.

3.15 All vaccinations should be deferred in a person with an acute febrile illness whose current temperature is 38.5 degrees Celsius or higher.

3.16 Oral vaccines, such as oral cholera vaccine, should be deferred in a person with diarrhoea and vomiting.

3.17 Live vaccines should not be given to members with immunosuppression, either due to an immunosuppressive illness or immunosuppressive medications. Live vaccines should be postponed until at least three months after cessation of treatment with high dose oral cortico-steroids (eg 60 mg per day). The Handbook provides additional information.

3.18 Vaccines containing live bacteria, such as the oral typhoid vaccine, may be less effective if the recipient is taking antibiotics or mefloquine. These vaccines should be given three days before antibiotics or mefloquine are taken.

3.19 A member who has had a previous severe adverse event (other than anaphylaxis) to a vaccine may be subsequently vaccinated with that vaccine under close medical supervision. However the risk of further vaccine doses must be assessed in relation to the potential benefit.
3.20 Administration of live attenuated virus vaccines should be deferred for three months after intramuscular administration of normal human immunoglobulin (NHIG) and for nine months after intravenous NHIG. No immunoglobulin product should be administered for at least two weeks after a live attenuated virus vaccine has been given. Table 2-1 lists these vaccines. Table 3-1—Immunoglobulin and antitoxin preparations lists immunoglobulin preparations currently available. However, Rh (D) immunoglobulin (anti-D) does not interfere with the antibody response to Measles, Mumps and Rubella (MMR) vaccines, and the two may be given at the same time in different sites with separate syringes or at any time in relation to each other.

Table 3-1: Immunoglobulin and antitoxin preparations

<table>
<thead>
<tr>
<th>IMMUNOGLOBULIN PREPARATIONS</th>
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<table>
<thead>
<tr>
<th>ANTITOXINS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria antitoxin</td>
</tr>
<tr>
<td>Equine heptavalent botulinum antitoxin</td>
</tr>
</tbody>
</table>

Notes:
(a) With the exception of human rabies immunoglobulin (Imogam Rabies) and anti-D immunoglobulin, there should be few situations where the immunoglobulin and antitoxin preparations listed in Table 3-1 are used in Defence members. Chapter 4—‘Vaccination requirements for Service personnel’ and the Handbook provide additional information.

3.21 Administration of live attenuated virus vaccines should be deferred for three months after whole blood transfusion.

3.22 In general, live vaccines should not be administered during pregnancy. The Australian Technical Advisory Group on Immunisation (ATAGI) takes the conservative position that the use of all vaccines should generally be avoided at any stage of pregnancy, since definitive studies on the level of risk have not been carried out. However, in some cases, such as influenza, the risk of the disease during pregnancy may outweigh the risk of vaccination and influenza vaccination is actively promoted to pregnant women. The Handbook provides guidance on the use of individual vaccines in pregnancy. Pregnant women are at liberty to discuss the use of vaccines with their obstetrician.
3.23 Administration of antitoxin produced from animal serum may cause hypersensitivity, manifesting as fever, serum sickness or anaphylaxis. Examples are diphtheria and botulism antitoxins. Test doses are administered according to the manufacturers’ instructions to indicate whether hypersensitivity is present. The Handbook refers.

Consent

3.24 Informed consent must be obtained in writing before any unregistered vaccine is administered. In the case of all other vaccinations consent is implied. The individual, or group, being vaccinated must be given adequate information to make an informed decision prior to submitting to vaccination. Individuals must be informed of:

a. which vaccine is to be administered;

b. the disease prevented by the vaccine;

c. the benefits and risks associated with the vaccine, including possible adverse events;

d. the need to inform medical staff if they answer in the affirmative to any question in the pre-vaccination checklist; and

e. the minimum post vaccination restrictions on activities.

Restrictions after vaccination

3.25 Members are to remain in the vicinity of the place of vaccination for at least 15 minutes after vaccination. Anaphylaxis is most likely to occur within the first 15 minutes but can occur up to several hours after vaccine administration. Before departure, vaccinated members should be informed of possible adverse events, action to take if an adverse event occurs and when the next scheduled vaccination is due.

3.26 Most vaccine adverse events are minor, but may interfere with members’ ability to participate in military activities. Injection site pain and swelling, low grade fever and malaise are common after many vaccines. These responses usually resolve within one or two days.

3.27 The following restrictions apply to all Defence members after any vaccination has been given:

a. In the hour following vaccination, it is recommended that members avoid driving, operating machinery, weapons handling or swimming.

b. In the 24 hours following vaccination, it is recommended that members avoid strenuous physical activity, eg. parachuting, combat survival course, fitness testing, or forced marches.

3.28 In addition, the following restrictions apply to aircrew and divers:

a. Aircrew are to be grounded for a minimum period of 12 hours following vaccination, or until all local or systemic reactions have passed. If an aircrew
member feels unwell beyond the 12-hour period, they are to consult with an Aviation Medical Officer (AVMO) before being cleared fit to resume flying duties.

b. Divers are not to dive for a minimum of 24 hours after vaccination or until all local and systemic reactions have passed.

**Adverse events following immunisation**

3.29 The term ‘adverse events following immunisation’ (AEFI) is advocated by the World Health Organization in preference to terms like ‘side effects’, ‘adverse effects’ and ‘adverse reactions’. It is preferred because it indicates a temporal relationship with immunisation, but not necessarily a causal relationship. An AEFI is an unwanted or unexpected event following immunisation. Most vaccines cause frequent minor adverse events. Mild events, such as fever, pain or redness at the site of injection, commonly follow immunisation with some vaccines and should be anticipated.

3.30 AEFI fall into three categories that are not mutually exclusive: local, systemic or allergic. Local reactions are the least severe and the most common. Systemic reactions (eg fever) occur less commonly than local reactions. Serious allergic reactions (such as anaphylaxis) are the least frequent but the most severe adverse event.

3.31 The frequency of adverse events can be classified as follows: very common (> 10%), common (1–10%), uncommon (0.1–1%), rare (0.01–0.1%) and very rare (<0.01%). The Handbook lists common adverse events associated with vaccines on the ASVS. The Product Information for each vaccine also has information on expected adverse events for that vaccine.

3.32 The most common immediate adverse event following immunisation in adults is a vasovagal episode (fainting). If symptoms suggesting the onset of fainting develop before or after vaccination the individual should be advised to lie down until free of symptoms. The most serious immediate adverse event is anaphylaxis. The features listed in Table 3-2—Clinical features which may assist differentiation between vasovagal (fainting) episode and anaphylaxis may be useful in differentiating between fainting and anaphylaxis.

**Table 3-2: Clinical features which may assist differentiation between a vasovagal (fainting) episode and anaphylaxis**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Vasovagal (fainting)</th>
<th>Anaphylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Onset</strong></td>
<td>Immediate—usually within minutes of or during vaccine administration.</td>
<td>Usually within 15 minutes, but can occur within hours, of vaccine administration.</td>
</tr>
<tr>
<td><strong>Respiratory</strong></td>
<td>Normal respiration; may be shallow, but not laboured.</td>
<td>Cough, wheeze, stridor, or signs of respiratory distress (tachypnoea, cyanosis, rib recession).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Upper airway swelling (lip, tongue, throat, uvula or larynx).</td>
</tr>
</tbody>
</table>
3.33 Rare late adverse events may be related to some vaccines, such as encephalopathy following MMR, related to the measles component.

3.34 Annex B lists the important adverse events associated with the routine vaccinations, comparing these with the effects of the disease.

3.35 Members receiving vaccinations are to be given instructions regarding any expected reactions or sequelae, and the care of any lesion resulting from the procedures.

### Treatment of adverse events following immunisation

3.36 All personnel administering vaccinations must be able to distinguish between convulsions and the immediate adverse events: fainting and anaphylaxis. The treatment of these three conditions is different.

3.37 Facilities for the emergency treatment of immediate adverse events following immunisation (AEFI) are to be available every time vaccines are administered. A MO must be within close proximity, for example, in the same building, be readily contactable and be able to attend within minutes. Personnel suitably qualified in the management of anaphylactic reactions, must be present at the time of vaccination. This may be a Military Advanced Resuscitation Course (MARC) qualified NO or an Advanced Medic. However, single-Service guidelines will dictate this requirement and must be followed.

3.38 A protocol for management of anaphylactic reactions is provided in annex C. It is based on guidance from the [Australian Resuscitation Council](http://www.resus.org.au/policy/guidelines/section_9/anaphylaxis_first_aid_managem).

3.39 Symptomatic treatment and/or temporary restriction of activity may be required for less serious AEFI.

Reporting adverse events following immunisation

3.40 Surgeon General Australian Defence Force requires that any adverse reactions to vaccines be reported, other than reactions which are anticipated common short-term side effects. Health Bulletin 1/2010 Adverse drug reaction reporting (http://intranet.defence.gov.au/home/documents/DATA/ADFPUBS/DHB/HB01_10.PDF) details the procedure to be followed.

3.41 Serological confirmation of post-vaccination immunity

3.42 Post-vaccination serological testing four weeks after the third dose of Hepatitis B vaccine should be done on health-care workers in accordance with the Handbook. Those at significant occupational risk who have a documented history of a completed primary schedule of Hepatitis B vaccine but in whom seroconversion status is unknown, should be given a single booster and tested for anti-HB levels four weeks later. Post-vaccination testing may indicate the need for further doses of vaccine and subsequent re-testing. This should be carried out in accordance with the protocol in the Handbook. Persistent non-responders should be informed about the need for post-exposure prophylaxis with Hepatitis B immunoglobulin (HBIG) within 72 hours of parenteral exposure to Hepatitis B virus.

Annexes:
A. Pre-vaccination assessment
B. Immunisation information
C. Medical management of anaphylactic reactions
ANNEX 3A

PRE–VACCINATION ASSESSMENT

1. The following information is needed to assess your fitness for vaccination. The conditions listed below do not necessarily mean that you cannot be vaccinated today, but please tell the nursing officer or medic if any of the following apply. You may be referred to a medical officer for further assessment if you:
   - are unwell today;
   - have a disease which lowers immunity (e.g., leukaemia, cancer, HIV/AIDS) or are having treatment which lowers immunity (e.g., steroid medicines such as cortisone and prednisone, radiotherapy and chemotherapy);
   - are living with someone who has a disease which lowers immunity, or living with someone who is having treatment which lowers immunity;
   - have had a severe reaction following any vaccine;
   - have any severe allergies (to anything);
   - have had a live vaccine within the last month (this includes measles-mumps-rubella vaccine, varicella (chickenpox) vaccine, yellow fever vaccine and oral typhoid vaccines);
   - have had an injection of immunoglobulin, or a whole blood transfusion within the last three months;
   - are pregnant or planning a pregnancy;
   - are breast feeding;
   - are living with someone who is not vaccinated;
   - will be flying or diving in the next 24 hours.

2. If the answer to any of these questions is ‘yes’, please inform the staff.

3. In the hour after vaccination, you should avoid driving, operating machinery, weapons handling or swimming.

4. In the 24 hours after vaccination, you should avoid strenuous physical activity, e.g., parachuting, combat survival course, fitness testing, or forced marches.

5. Before any vaccination takes place, the immunisation provider will ask you if you understand the information provided to you about immunisation and whether you need more information.

6. You will be required to remain at the health facility for at least 15 minutes after vaccination for observation.

7. This Checklist is also available as a Web Form PM 573—Vaccination Checklist. (http://intranet.defence.gov.au/webforms/form?pm573)
## ANNEX 3B
### IMMUNISATION INFORMATION

<table>
<thead>
<tr>
<th>Disease</th>
<th>Effects of disease</th>
<th>Side effects of vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diphtheria</strong>—contagious bacteria spread by droplets; causes severe throat and breathing difficulties.</td>
<td>Up to 1 in 7 patients dies. The bacteria release a toxin, which can produce nerve paralysis and heart failure.</td>
<td>About 1 in 10 has local swelling, redness or pain at the injection site, or fever (DTPa/dTpa vaccine). Booster doses of DTPa may occasionally be associated with extensive swelling of the limb, but this resolves completely within a few days. Serious adverse events are very rare.</td>
</tr>
<tr>
<td><strong>Hepatitis A</strong>—virus spread mainly by faecal-oral route.</td>
<td>At least 7 in 10 adult patients develop jaundice (yellowing of the skin and eyes), fever, anorexia (decreased appetite), nausea, vomiting, hepatic (liver) pain and malaise (tiredness).</td>
<td>About 1 in 5 will have local swelling, redness or pain at the injection site. Serious adverse events are very rare.</td>
</tr>
<tr>
<td><strong>Hepatitis B</strong>—virus spread mainly by blood, sexual contact or from mother to newborn baby, causes acute hepatitis or chronic carriage.</td>
<td>About 1 in 4 chronic carriers will develop cirrhosis or liver cancer.</td>
<td>About 1 in 20 will have local swelling, redness or pain at the injection site and 2 in 100 will have fever. Anaphylaxis occurs in about 1 in 1 million. Serious adverse events are very rare.</td>
</tr>
<tr>
<td><strong>Human papillomavirus</strong>—virus spread mainly via sexual contact; up to 80% of the population will be infected with HPV at some time in their lives. Some HPV types are associated with the development of cancer.</td>
<td>About 7 in 10 cervical cancers worldwide have been associated with HPV-16 and 1 in 6 with HPV-18.</td>
<td>About 8 in 10 will have pain and 2 in 10 will have local swelling, redness or pain at the injection site. Headache, fever, muscle aches and tiredness may occur in up to 3 in 10 people. Serious adverse events are very rare.</td>
</tr>
<tr>
<td><strong>Influenza</strong>—virus spread by respiratory droplets; causes fever, muscle and joint pains, pneumonia. About 1 in 10 to 1 in 5 persons will get influenza every year.</td>
<td>There are an estimated 3000 deaths in people older than 50 years of age each year in Australia. Causes increased hospitalisation in the very young and the elderly. Other high-risk groups include pregnant women, people who are obese, diabetics and others with certain chronic medical conditions.</td>
<td>About 1 in 10 has local swelling, redness or pain at the injection site. Fever occurs in about 1 in 10 children aged 6 months to 3 years. Guillian-Barré syndrome occurs in about 1 in 1 million. Serious adverse events are very rare.</td>
</tr>
<tr>
<td>Disease</td>
<td>Risk Factors</td>
<td>Symptoms/Complications</td>
</tr>
<tr>
<td>-------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Japanese Encephalitis</td>
<td>mosquito-borne virus; causes acute nervous system disease with headache, fever, convulsions, decreased level of consciousness, coma.</td>
<td>Mortality up to 30%. No specific treatment available. About 60% of survivors have permanent nervous system damage.</td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
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</tr>
<tr>
<td>Measles</td>
<td>highly infectious virus spread by respiratory droplets; causes fever, cough and rash.</td>
<td>About 1 in 15 children with measles develops pneumonia and 1 in 1000 develops encephalitis (brain inflammation). For every 10 children who develop measles encephalitis, 1 dies and many have permanent brain damage. About 1 in 100 000 develops SSPE (brain degeneration), which is always fatal.</td>
</tr>
<tr>
<td>Meningococcal infections</td>
<td>bacteria spread by respiratory droplets; causes septicaemia (infection of the blood stream) and meningitis (infection of the tissues surrounding the brain).</td>
<td>About 1 in 10 patients dies. Of those that survive, 1 to 2 in 10 have permanent long-term problems, such as loss of limbs and brain damage.</td>
</tr>
<tr>
<td>Mumps</td>
<td>virus spread by saliva; causes swollen neck and salivary glands, and fever.</td>
<td>One in 5000 children develops encephalitis (brain inflammation). One in 5 males (adolescent/adult) develop inflammation of the testes. Occasionally, mumps causes infertility or permanent deafness.</td>
</tr>
<tr>
<td>Pertussis</td>
<td>bacteria spread by respiratory droplets; causes 'whooping cough', with prolonged cough lasting up to 3 months.</td>
<td>About 1 in 125 babies under the age of 6 months with whooping cough dies from pneumonia or brain damage.</td>
</tr>
</tbody>
</table>
### Pneumococcal Infection
- **Bacteria** spread by respiratory droplets; causes septicaemia (infection of the blood stream), meningitis (infection of the tissues surrounding the brain) and occasionally other infections.
- About 3 in 10 people with meningitis die.
- One-third of all pneumonia cases and up to half of pneumonia hospitalisations in adults is caused by pneumococcal infection.
- About 1 in 5 has local swelling, redness or pain at the injection site, or fever (conjugate vaccine).
- Up to 1 in 2 has local swelling, redness or pain at the injection site (polysaccharide vaccine).
- Serious adverse events are very rare.

### Polio
- Contagious virus spread by faeces and saliva; causes fever, headache, vomiting and may progress to paralysis.
- While many infections cause no symptoms, up to 3 in 10 patients with paralytic polio die, and many patients who survive are permanently paralysed.
- IPV: Local redness, pain and swelling at the injection site are common.
- Up to 1 in 10 has fever, crying and decreased appetite. Serious adverse events are very rare.

### Rabies
- Deadly viral infection of the brain transmitted by bites/scratches from infected animals—especially dogs and cats, also bats (Australian bat Lyssavirus). Causes agitation, bizarre behaviour, fits, muscle spasms, eventually coma and death.
- Almost always fatal.
- Sore arm (15 to 25%), headache (5 to 8%), malaise, nausea or both (2 to 5%), and allergic oedema (in 0.1%). Anaphylaxis rare, 6% of persons receiving booster doses may have allergic reactions.

### Rubella
- Contagious virus spread by droplets; causes fever, rash, swollen glands, but causes severe malformations in babies of infected pregnant women.
- Patients typically develop a rash, painful swollen glands and painful joints. One in 3000 develops low platelet count (causing bruising or bleeding); 1 in 6000 develops encephalitis (brain inflammation).
- Up to 9 in 10 babies infected during the first trimester of pregnancy will have a major congenital abnormality (including deafness, blindness or heart defects).
- About 1 in 10 has local swelling, redness or pain at the injection site.
- About 1 in 20 has swollen glands, stiff neck or joint pains. About 1 in 20 has a rash, which is non-infectious.
- Low platelet count (causing bruising or bleeding) occurs after the 1st dose of MMR vaccine, at a rate of about 1 in 20,000 to 30,000.
- Serious adverse events are very rare.

### Tetanus
- Caused by toxin of bacteria in soil; causes painful muscle spasms, convulsions, lockjaw.
- About 2 in 100 patients die. The risk is greatest for the very young or old.
- About 1 in 10 has local swelling, redness or pain at the injection site, or fever (DTPa/dTpa vaccine). Booster doses of DTPa may occasionally be associated with extensive swelling of the limb, but this resolves completely within a few days. Serious adverse events are very rare.
<table>
<thead>
<tr>
<th>Disease</th>
<th>Description</th>
<th>Complications and Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Typhoid</strong></td>
<td>spread by faecal-oral route, through contaminated food or drink.</td>
<td>Complications of gastrointestinal bleeding, intestinal perforation or typhoid encephalopathy in 10-15% of cases. Up to 10% relapse. Up to 5% become chronic carriers. Usually mild and transient. Local erythema, swelling and pain at the injection site occur very commonly in 10 to 20%. Systemic adverse events are common and include fever (3%), malaise and nausea.</td>
</tr>
<tr>
<td><strong>Varicella (chickenpox)</strong></td>
<td>caused by highly contagious virus; causes low-grade fever and vesicular rash. Reactivation of the virus later in life causes herpes zoster (shingles).</td>
<td>One in 100 000 patients develops encephalitis (brain inflammation). Infection during pregnancy can result in congenital malformations in the baby. Infection in the mother around delivery time results in severe infection in the newborn baby in up to one-third of cases. About 1 in 5 has a local reaction or fever. About 3 to 5 in 100 may develop a mild varicella-like rash. Serious adverse events are very rare.</td>
</tr>
<tr>
<td><strong>Yellow Fever</strong></td>
<td>a severe viral haemorrhagic fever spread by mosquito bites. Causes fever, vomiting, jaundice (yellow skin) and bleeding.</td>
<td>Case fatality rate varies greatly; can be over 20%. Mild symptoms, including headaches, muscle aches, low-grade fevers, or other minor symptoms are common, occurring 5–10 days after vaccination. Encephalitis (brain inflammation) occurs very rarely—about 1 in 8 million—and full recovery is usual. Disease of several organs resulting in death has occurred very rarely. Risk greatest in those aged &gt;60 years.</td>
</tr>
</tbody>
</table>
ANNEX 3C

MEDICAL MANAGEMENT OF ANAPHYLACTIC REACTIONS

CLINICAL RECOGNITION

Early
- sensations of warmth, itching especially in axillae and groins
- feelings of anxiety or panic

Progressive
- erythematous or urticarial rash
- swelling of face, lips and eyes
- tingling mouth
- stomach pain or vomiting

Severe
- persistent dizziness or collapse
- hypotension (shock)
- bronchospasm (wheezing), difficult or noisy breathing or cough
- swelling/tightness in throat (dyspnoea, stridor, aphonia, drooling)
- difficulty talking, hoarse voice
- arrhythmias, cardiac arrest

Note

The onset of severe clinical features may be extremely rapid without prodromal features.

ACUTE MANAGEMENT

1. Immediate action
- Remove allergen if still present
- Call for assistance
- Lay patient flat. Do not allow them to stand or walk. If breathing is difficult allow them to sit.

2. Administer intramuscular adrenaline
- Administer 0.5 ml of adrenaline (1:1000 containing 1 mg per 1 ml) by intramuscular injection (lateral thigh)
- An adrenaline autoinjector (EpiPen) may be used instead of an adrenaline ampoule and syringe
- Administration of adrenaline is life saving and must not be delayed.
3. **Call ambulance to transport patient if required**

4. **Supportive management**
   - Monitor pulse, blood pressure, respiratory rate, pulse oximetry
   - Give high flow oxygen and airway support if needed
   - Obtain intravenous access
   - If hypotensive, give intravenous normal saline (20 mL/kg rapidly) and consider additional wide bore intravenous access

5. **Additional measures**

   **Adrenaline infusion**

   If facilities and available expertise allow, an adrenaline infusion may be considered for those with inadequate response or deterioration.

   **Adrenaline infusions should only be given in liaison with an emergency medicine/critical care specialist.**

   Adrenaline infusion procedure:
   - Mix 1 mL of 1:1000 adrenaline in 1000 mL of normal saline
   - Start infusion at ~5 mL/kg/hour (~0.1 microgram/kg/minute)
   - Titrate rate according to response
   - Monitor continuously

   **CAUTION**—Intravenous boluses of adrenaline are not recommended due to the risk of cardiac arrhythmia

   If adrenaline infusion is ineffective or unavailable, consider:

   **For upper airway obstruction**
   - Nebulised adrenaline (5 mL ie 5 ampoules of 1:1000)
   - Consider intubation if skills and equipment are available

   **For persistent hypotension/shock**
   - Give normal saline (maximum 50 mL/kg in the first 30 min)
   - In patients with cardiogenic shock (especially if taking beta blockers) consider an intravenous glucagon bolus of 1–2 mg in adults (in children: 20–30 microgram/kg up to 1 mg). This may be repeated or followed by an infusion of 1–2 mg/hour in adults
   - In adults, selective vasoconstrictors metaraminol (2–10 mg) or vasopressin (10–40 units) only after advice from an emergency medicine/critical care specialist.

   **For persistent wheeze**
   - Bronchodilators: Salbutamol 8–12 puffs of 100 microgram using a spacer or 5 mg salbutamol by nebuliser
• Oral prednisolone 1 mg/kg (maximum 50 mg) or intravenous hydrocortisone 5 mg/kg (maximum 200 mg)

6. Observation

Prolonged and biphasic reactions may occur. Observe the patient for at least four hours after the last dose of adrenaline.

Admit for overnight observation if the patient:
• had a severe reaction (hypotension or hypoxia) or
• required repeated doses of adrenaline or
• has a history of asthma or protracted anaphylaxis or
• has other concomitant illness or
• lives alone or in living-in accommodation, or is remote from medical care

7. Follow-up treatment

Antihistamines

Antihistamines have no role in treating respiratory or cardiovascular symptoms of anaphylaxis. Oral non-sedating antihistamines may be given to treat itch and urticaria. Injectable promethazine should not be used in anaphylaxis as it can worsen hypotension and cause muscle necrosis.

Corticosteroids

The role of corticosteroids is unknown. It is reasonable to prescribe a two day course of oral steroid (eg prednisolone 1 mg/kg, maximum 50 mg daily) to reduce the risk of symptom recurrence after a severe reaction or a reaction with marked or persistent wheeze.

Adrenaline autoinjector

Prescribe an autoinjector, pending specialist review. Train the patient in autoinjector use and give them an ASCIA Action Plan for Anaphylaxis (see Australasian Society of Clinical Immunology and Allergy website (www.allergy.org.au)).

Allergy specialist referral

Refer patients with anaphylaxis for specialist review.
References:

Australian Resuscitation Council

Australasian Society of Clinical Immunology and Allergy

The Anaphylaxis Emergency management for health professionals wall chart
(http://www.australianprescriber.com/magazine/34/4/article/1210.pdf)
CHAPTER 4

VACCINATION REQUIREMENTS FOR SERVICE PERSONNEL

INTRODUCTION

4.1 This chapter outlines the routine and additional vaccination requirements for permanent force and reserve members of the Australian Defence Force (ADF). It also provides guidance on vaccination of dependants of Defence members and authorised civilians.

ROUTINE VACCINATIONS

4.2 Defence members require vaccination against a number of infectious diseases to be fit for deployment. Currency in or completion of the routine vaccinations is required for any deployment. These vaccinations include those on the Australian standard vaccination schedule (ASVS) and those for certain diseases, such as hepatitis A and typhoid, which are considered a threat for any deployment. The ASVS is detailed in the current edition of the Australian Immunisation Handbook (http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home) (the Handbook). Table 4.1 lists the routine vaccinations.

4.3 As soon as practicable after entry into full-time service in the ADF, personnel are to complete primary schedules for the routine vaccines listed in Table 4.1, unless they provide evidence that they have already completed primary schedules. The Handbook provides the primary schedules for those vaccines on the ASVS. If primary schedules have been completed, personnel need only be vaccinated in accordance with the ‘Doses after primary schedule’ column.

4.4 Where an individual provides evidence of a partially complete primary schedule, the schedule is not to be started again, regardless of the interval since previous doses. Rather, the aim is to build on documented doses so that the total number of required doses is given. If no documentation of previous doses is available, the total number of primary schedule doses is to be given. The ‘Primary schedule dose requirements’ and ‘Comments’ columns of Table 4.1 provide guidance on catch-up regimens.

ADDITIONAL VACCINATIONS

4.5 Defence members may require vaccines in addition to the routine vaccines. Table 4.2 lists the additional vaccines.

4.6 Additional vaccinations may be required for deployment if there is a known environmental disease threat. This may include specific vaccinations in response to a perceived threat from biological warfare agents. Orders for the administration of these vaccines will be promulgated as required from the relevant environmental command.
4.7 Defence members may be required to have additional vaccinations to maintain immunity to diseases in order to meet operational readiness requirements, particularly for overseas service. An example is Japanese encephalitis vaccine. Owing to environmental factors or individual attributes, some personnel are at higher risk for certain diseases. Examples are influenza vaccine and meningococcal C conjugate vaccine.

4.8 Defence members authorised to undertake recreational travel are entitled to receive vaccinations that are clinically indicated for the area being visited at Service expense. This entitlement however, does not include the member’s dependants.

4.9 Members required for chemical, biological and radiological operations might need to be vaccinated beyond the normal operational vaccination requirements. Vaccines to be given to these personnel will be approved by the Surgeon General Australian Defence Force (SGADF) and promulgated by Headquarters Joint Operations Command/environmental commands.

4.10 Members may require particular vaccinations because they have increased susceptibility to certain diseases. Examples include 23-valent pneumococcal polysaccharide vaccine, influenza vaccine and meningococcal C conjugate vaccine.

4.11 The validity of a yellow fever vaccination record in the International Certificates of Vaccination (ICV) extends for 10 years, commencing 10 days after the date of vaccination, or in the case of revaccination before the expiry of the previous certificate, from the date of that revaccination. It is valid only if the vaccine used has been approved by the World Health Organization (WHO) and if the vaccine has been administered by or under the direct supervision of an approved yellow fever vaccination provider.

4.12 A number of Defence health facilities have health care professionals who are approved yellow fever vaccination providers. A current list can be obtained from the Director Health Service Delivery (DHSD) and is available on the DHSD page on the JHC intranet site. Defence health facilities, which have a requirement to administer yellow fever vaccine, may apply to their respective State/Territory Health Department for accreditation as an authorised vaccination centre. Any such accreditation is to be advised to the DHSD via email at mailto:JHC-GHO@defence.gov.au. Defence health facilities, which are granted this accreditation, must ensure that they have, and use, the authorised stamp to validate each immunisation.

NOTES FOR SPECIFIC VACCINES

4.13 The requirement for ten-yearly boosters for diphtheria-tetanus-pertussis (dTpa) is different from the ASVS, in that routine adult boosting has not yet been recommended in Australia. Defence members are at risk of exposure to these diseases on deployment to overseas countries. Boosting with dTpa is recommended for pregnant women in the third trimester and for adult household contacts and carers of infants. See the Handbook for details.

4.14 An exception to the requirement for three doses of Hepatitis B vaccine occurs where an individual has had one dose of adult formulation H–B–0Vax II before the 16th birthday as part of a two-dose schedule. In this case, only one dose of monovalent Hepatitis B vaccine is required to complete the primary schedule.
4.15 Members who provide evidence of completed accelerated schedule for either the combined hepatitis vaccine or Hepatitis B monovalent vaccine as described in the Handbook are to be regarded as having completed the primary schedule.

4.16 Seasonal influenza vaccination is recommended for all Defence members. It is voluntary unless listed in the health support order for a particular deployment. Members considered to be particularly at risk for influenza are:

a. those recruited prior to and during the influenza season;
b. members who will be at training establishments during the influenza season;
c. ships’ personnel;
d. health care workers;
e. members deploying to an area where the influenza season is current; and
f. members deploying to the tropics at any time of year.


4.18 Meningococcal vaccines. The C conjugate and quadrivalent conjugate meningococcal vaccines (A, C, W135, Y) are not to be used interchangeably. Defence members may require both types of vaccine for the different indications—at risk in Australia (C conjugate) and subsequently deploying to areas where epidemics of A, W135 or Y disease occur (quadrivalent vaccine). The Handbook provides additional information.

4.19 Japanese encephalitis (JE) vaccines. IMOJEV® is the preferred vaccine for Defence members as it is a single dose schedule. A seroprotective level of antibodies is generally reached 14 days after vaccination. JESPECT® is an alternative to IMOJEV® for the primary immunisation of Defence members against JE. The primary course consists of two injections 28 days apart, with a booster in the 12–24 months after the primary course. JESPECT® may be used where IMOJEV® is unavailable or contra-indicated, or to complete a primary course that has been started. More detail regarding dosing schedules and precautions is in the Handbook and the Product Information.

Human papillomavirus vaccine

4.20 The preferred human papillomavirus vaccine in the ADF is 4-valent HPV vaccine (Gardasil®). This vaccine does not treat existing infection with any of the HPV vaccine strains, nor does it offer any protection against other sexually transmitted infections.
4.21 Vaccination with HPV vaccine is not a Service or deployment requirement and will not affect members’ Medical Employment Classification or Individual Readiness. Vaccination is voluntary and risks and benefits for each individual should be assessed and discussed prior to vaccination. The decision to offer vaccination should be based on individual need, as determined during either routine consultation or associated screening activities (eg Pap smear, sexual health check).

4.22 The National HPV Vaccination Program Register ([National HPV Register](http://www.hpvregister.org.au/health-professionals.aspx)) collects data about the program to evaluate the impact of the HPV Vaccination Program on rates of cervical and other cancers and other HPV related conditions and to issue reminders to vaccine recipients. Participation in the National HPV Register is voluntary and members can decline to have their details included in the Register. The nominated contact personnel from each Joint Health Unit/Health Centre are to enter consenting members’ details directly into the National HPV Register. There are no additional reporting requirements for HPV vaccination.

**Table 4.1: Routine vaccinations**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Vaccines(a)</th>
<th>Dose</th>
<th>Doses after primary schedule(b)</th>
<th>Primary schedule dose requirements</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria, Tetanus, Pertussis</td>
<td>Adult/adolescent formulation of diphtheria-tetanus-acellular pertussis (dTpa)</td>
<td>0.5 ml IM</td>
<td>1 dose at age 15–17 or instead of a dT dose. 1 dose every 10 years in place of dT.</td>
<td>A total of 3 doses of dT, 4 weeks between doses.</td>
<td>dTpa gives additional protection against pertussis. dTpa may be used preferentially for the first dose of a catch up primary schedule for diphtheria and tetanus immunisation. dTpa is recommended for women in the third trimester of pregnancy or immediately post partum. Similarly, dTpa is recommended for carers of infants.</td>
</tr>
<tr>
<td></td>
<td>Adult diphtheria-tetanus (dT)</td>
<td>0.5 ml IM</td>
<td>1 dose every 10 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poliomyelitis</td>
<td>Inactivated poliomyelitis vaccine (IPV)</td>
<td>0.5 ml SC</td>
<td>1 dose only if going to polio-endemic area</td>
<td>A total of 3 doses. 4 weeks between doses.</td>
<td>After the primary schedule is complete, booster dose only required if deploying or travelling to a polio endemic area and last dose was &gt;10 years ago or as directed in Health Support Order.</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>Monovalent Hepatitis B</td>
<td>1 ml IM</td>
<td>None</td>
<td>A total of 3 doses. Minimum 1 month</td>
<td>All personnel are to complete or provide proof of a completed primary schedule of vaccination for Hepatitis A, Hepatitis B and Typhoid. The combined vaccines may be substituted for monovalent vaccines to decrease the total number of injections required. Where an individual has started with a monovalent vaccine, the primary schedule for the monovalent vaccine should be completed. With the combined typhoid Vi polysaccharide and Hepatitis A vaccine a dose of monovalent Hepatitis A vaccine is required at six months to provide long term immunity.</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Combined adult Hepatitis A and B</td>
<td>1 ml IM</td>
<td>None</td>
<td>between doses 1 and 2, 5 months between doses 2 and 3.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monovalent hepatitis A</td>
<td>1 ml IM</td>
<td>None</td>
<td>2 doses at least 6 months apart.</td>
<td></td>
</tr>
<tr>
<td>Typhoid</td>
<td>Combined typhoid Vi polysaccharide and hepatitis A</td>
<td>1 ml IM</td>
<td>None</td>
<td>1 dose</td>
<td></td>
</tr>
<tr>
<td>Disease</td>
<td>Vaccine(a)</td>
<td>Dose</td>
<td>Doses after primary schedule(b)</td>
<td>Primary schedule dose requirements</td>
<td>Comments</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-----------------------------------</td>
<td>-----------------</td>
<td>---------------------------------</td>
<td>-----------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Typhoid Vi polysaccharide</td>
<td>0.5 ml IM</td>
<td>1 dose every 3 years.</td>
<td>1 dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measles, Mumps and Rubella</td>
<td>Measles-mumps-rubella (MMR)</td>
<td>0.5 ml IM or SC</td>
<td>None</td>
<td>2 doses at least 1 month apart.</td>
<td>Personnel born during or since 1966 are to have a total of two doses or provide proof of having had two doses. Persons born before 01 January 1966 are presumed to have immunity.</td>
</tr>
<tr>
<td>Varicella-Zoster</td>
<td>Varicella-zoster vaccine (VZV)</td>
<td>0.5 ml SC</td>
<td>None</td>
<td>2 doses: 1 to 2 months apart.</td>
<td>Required for non-immune persons. These are persons who do not have a clear history of chicken pox, or who have negative varicella-zoster virus serology. If there is a history of chicken pox, then immune status is assumed.</td>
</tr>
</tbody>
</table>

Notes:
(a) The preferred term or abbreviation for the vaccine, if such exists in the Handbook, is provided in this column.
(b) The schedules indicate the minimum allowable dosage intervals. The use of longer intervals between doses does not impair the immunogenicity of the vaccines.
(c) The reason for recommending that dTpa be given as the first dose of a catch-up schedule is that if a reaction occurs, and a decision is made not to give any further doses of vaccine containing diphtheria antigen, the person will have had their one dose of adult pertussis vaccine. For a similar reason dTpa should preferably be given as early as possible in a catch-up schedule which has already commenced.

Table 4.2: Additional vaccines

<table>
<thead>
<tr>
<th>Disease</th>
<th>Vaccine(a)</th>
<th>Dose(b)</th>
<th>Schedule</th>
<th>Indication for use</th>
<th>Comments</th>
</tr>
</thead>
</table>

Must be used in accordance with the Investigational New Drug requirements of the US Food and Drug Administration and Centers for Disease Control and Prevention. Chapter 5 refers.
<table>
<thead>
<tr>
<th>Disease</th>
<th>Vaccine(a)</th>
<th>Dose(b)</th>
<th>Schedule</th>
<th>Indication for use</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholera</td>
<td>Oral cholera vaccine (Dukoral)</td>
<td>1 sachet PO</td>
<td>2 doses: 0, 1 wk. Repeat primary course if boosting required, 2-yearly</td>
<td>Health Support Order or as recommended for overseas travel</td>
<td>Greatest benefit when vaccinated in adolescence. May be provided where clinical opinion is that it would benefit the member. Where the member agrees, dose administration should be reported to the National HPV Register. HPV vaccination does not obviate the need for ongoing PAP screening in women.</td>
</tr>
<tr>
<td>Human Papillomavirus</td>
<td>4-valent HPV vaccine (Gardasil)</td>
<td>0.5 ml IM</td>
<td>3 doses: 0, 2 months, 6 months.</td>
<td>Prevention of infection with HPV vaccine virus strains. Women up to age 45 yrs, men up to age 26 yrs.</td>
<td></td>
</tr>
<tr>
<td>Influenza</td>
<td>Influenza vaccine</td>
<td>0.5 ml IM</td>
<td>1 dose. Annual re-vaccination.</td>
<td>At risk personnel, Health support order or as recommended for overseas travel.</td>
<td>Recommended for all personnel. Strongly recommended for pregnant women, personnel with chronic medical conditions, those living with vulnerable people. Mandatory for groups listed in paragraph 4.16.</td>
</tr>
<tr>
<td>Invasive pneumococcal disease</td>
<td>13-valent pneumococcal conjugate vaccine (13vPCV)</td>
<td>0.5 ml IM</td>
<td>1 dose</td>
<td>Splenectomy. Handbook lists other indications and dosing schedule.</td>
<td>Members with absent or dysfunctional spleen (and for other indications as detailed in the handbook) require one dose of the 13vPCV in addition to 23vPPV for the prevention of IPD. Timings are detailed in the handbook.</td>
</tr>
<tr>
<td>Japanese encephalitis</td>
<td>Japanese encephalitis (Imojev)</td>
<td>0.5 ml SC</td>
<td>1 dose</td>
<td></td>
<td>Protection likely to last at least 5 years. Longer term boosting requirements not yet determined.</td>
</tr>
<tr>
<td></td>
<td>Japanese encephalitis vaccine (JEspect)</td>
<td>0.5 ml IM</td>
<td>2 doses: 0, 28 days. Booster of single dose if more than 12 months since primary course and at ongoing risk of JE.</td>
<td></td>
<td>Protection is likely to last 3-4 years after the third dose. Longer term boosting requirements not yet determined.</td>
</tr>
<tr>
<td>Meningococcal disease due to strain C</td>
<td>Meningococcal C conjugate vaccine</td>
<td>0.5 ml IM</td>
<td>1 dose</td>
<td>Students, trainees and staff living in close proximity in barracks style accommodation who have not previously received this vaccine.</td>
<td>In an outbreak situation, depending on the strain involved, vaccine may be given in accordance with the Invasive Meningococcal Disease Guidelines for Public Health Units.</td>
</tr>
<tr>
<td>Disease</td>
<td>Vaccine&lt;sup&gt;(a)&lt;/sup&gt;</td>
<td>Dose&lt;sup&gt;(b)&lt;/sup&gt;</td>
<td>Schedule</td>
<td>Indication for use</td>
<td>Comments</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>------------------------------</td>
<td>------------------------</td>
<td>---------------------------</td>
<td>------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Meningococcal disease due to strains A, C, W135 and Y</td>
<td>4-valent meningococcal conjugate vaccine</td>
<td>0.5 ml IM</td>
<td>1 dose. Boost with single dose every 5 years as required.</td>
<td>Health Support Order or as recommended for overseas travel.</td>
<td><em>(<a href="http://www.health.gov.au/internet/main/publishing.nsf/Content/cdna-song-IMD.htm">http://www.health.gov.au/internet/main/publishing.nsf/Content/cdna-song-IMD.htm</a>)</em></td>
</tr>
<tr>
<td>Plague</td>
<td>Plague vaccine</td>
<td>0.5 ml SC</td>
<td>2 doses: 0, 28 days. Booster every 6 months if required.</td>
<td>Health Support Order</td>
<td>Used in persons engaged in field operations or resident in plague enzootic areas where preventing exposure cannot be assured. Antibiotic prophylaxis as well if very high risk.</td>
</tr>
<tr>
<td>Q fever</td>
<td>Q fever vaccine</td>
<td>0.5 ml SC</td>
<td>1 dose</td>
<td>Health Support Order</td>
<td>Contraindicated in: persons with history of proven or suspected Q fever; previously vaccinated; proven immunity; allergy to eggs. Prevaccination testing may be required.</td>
</tr>
<tr>
<td>Rabies</td>
<td>Rabies vaccine</td>
<td>1 ml IM in deltoid</td>
<td>3 doses: 0, 7, 28 days. Booster every 2 years if required.</td>
<td>Land based high risk personnel (preventive medicine personnel, military dog handlers and personnel trained in feral animal capture and euthanasia) on 28 days or less notice to move. Health Support Order</td>
<td>Additional doses required after exposure to rabies or Australian Bat Lyssavirus. Paragraph 4.14 refers. See handbook for more detail.</td>
</tr>
<tr>
<td>Yellow Fever</td>
<td>Yellow fever vaccine</td>
<td>0.5 ml IM or SC</td>
<td>1 dose. Duration of protection: 10 years.</td>
<td>Health Support Order or as recommended for overseas travel.</td>
<td></td>
</tr>
<tr>
<td>Zoster (Herpes Zoster)</td>
<td>Zoster vaccine (Zostavax)</td>
<td>0.65 ml SC</td>
<td>1 dose</td>
<td>Personnel aged 60 yrs or more who have not received zoster vaccine previously.</td>
<td>Not recommended if have previously received varicella vaccine. May be recommended by specialist for younger personnel with conditions likely to compromise the immune system. See handbook for details.</td>
</tr>
</tbody>
</table>

**Notes:**

(a) Vaccines are referred to generically. Brand names for vaccines are given where there is a difference in administration or duration of protection of different brands.

(b) Once the primary schedule has been completed, it is not to be restarted for any reason. For example, if the duration between boosters exceeds the recommended period, it is to be assumed that the single booster dose will provide adequate immunity.
POST-EXPOSURE PROPHYLAXIS VACCINATION REQUIREMENTS

4.23 In some situations, Defence members may require vaccination, immunoglobulin and/or antitoxin preparations after exposure to an infective agent. **Table 3.1** lists the available immunoglobulins and antitoxins. Defence members are most likely to require post-exposure prophylaxis after tetanus-prone wounds and after contact with rabies or the Australian Bat Lyssavirus (ABL).

4.24 In the event of a tetanus-prone injury a booster dose of vaccine, given either as dT or dTpa, should be given if more than five years have elapsed since the last dose. If the member has not had a previous dose of dTpa, then this is the preferred vaccine. Types of wounds likely to favour the growth of tetanus organisms include compound fractures, deep penetrating wounds, wounds containing foreign bodies (especially wood splinters), wounds complicated by pyogenic infections, wounds with extensive tissue damage (e.g., contusions or burns) and any superficial wound obviously contaminated with soil, dust or horse manure (especially if topical disinfection is delayed more than four hours). Re-implantation of an avulsed tooth is also a tetanus-prone event, as minimal washing and cleaning of the tooth is conducted to increase the likelihood of successful re-implantation. There should be no requirement for tetanus immunoglobulin in Defence members unless they sustain a wound during catch-up vaccination.

4.25 Defence members who are persistent non-responders on testing for serological confirmation of post-vaccination immunity to hepatitis B require post-exposure prophylaxis with Hepatitis B immunoglobulin (HBIG) within 72 hours of parenteral exposure to Hepatitis B virus. The Handbook provides additional information.

4.26 The essential components of post-exposure prophylaxis following either ABL or rabies exposures are prompt local wound management and administration of human rabies immunoglobulin (HRIG) and/or rabies vaccine. Post-exposure prophylaxis should be considered whenever a bite, scratch or mucous membrane exposure to saliva from any Australian bat or any possibly infected animal in a rabies endemic country has occurred. It should be commenced as soon as possible after a possible exposure. Post-exposure prophylaxis is most effective if commenced within 48 hours, although it should be given regardless of the time since the possible exposure.

4.27 Post-exposure prophylaxis is determined by the category of exposure and immune status as detailed in the Handbook. **Table 4.3** summarises the post-exposure prophylaxis for category II and III ABL and rabies exposures. Category I exposures do not require prophylaxis if the contact history is reliable. It should be noted that rabies has occurred in people who have not received the complete post-exposure prophylaxis recommended for the category of exposure.
Table 4.3: Post-exposure prophylaxis for Category II and III Australian Bat Lyssavirus and rabies exposures

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Immediate</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Immune persons</td>
<td>Rabies vaccine</td>
<td>1 ml IM</td>
</tr>
<tr>
<td>— all category II and III exposures</td>
<td></td>
<td>1 ml IM on days 3, 7, 14 (4 doses in total). Immunocompromised individuals need a further dose on day 30 (5 doses in total)</td>
</tr>
<tr>
<td>HRIG — categories II and III ABL and category III rabies exposures</td>
<td>20 IU/kg. Infiltrate as much as possible of calculated dose in and around the wound. Give remainder IM away from vaccine injection site. Do not give if more than 8 days have passed since the first dose of vaccine.</td>
<td></td>
</tr>
<tr>
<td>Immune persons</td>
<td>Rabies vaccine</td>
<td>1 ml IM</td>
</tr>
<tr>
<td>— Rabies vaccine on day 3 (2 doses in total)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes:
(a) Thorough wound cleansing, including application of a virucidal preparation such as povidone-iodine solution, is required in all cases.
(b) Immune persons are those who have either completed a recommended course of pre-exposure prophylaxis, or previous post-exposure treatment, or who have documented adequate rabies neutralising antibodies.
(c) Routine malaria chemoprophylaxis does not make an individual ‘immunocompromised’.

VACCINATION REQUIREMENTS FOR MEMBERS OF THE RESERVE FORCES

4.28 Reserve force members are to make their own arrangements to ensure that they are current with the ASVS, and that they have been vaccinated against Hepatitis B. They are to be informed of this requirement during their Periodic Health Assessment. However, Defence will provide vaccinations for Reserve force members who have been recommended by their unit for Continuous Full Time Service (CFTS) in accordance with Table 4.1.

4.29 Vaccinations for Reserve members serving on other than CFTS are to be provided in accordance with HD 284—Medical assessments and dental examination requirements for Australian Defence Force Reserve personnel (http://intranet.defence.gov.au/home/documents/data/ADFPUBS/HPD/HD284.PDF) and single Service policies or at the request of the Service or Operational Headquarters for individual or unit readiness.
VACCINATION OF CONTRACT HEALTH PRACTITIONERS

4.32 Vaccination of contract health practitioners (CHP), including medical, nursing, other health professionals and laboratory staff, is not funded by Defence. CHP are responsible for their own vaccinations.

INTERNATIONAL VACCINATION REQUIREMENTS

4.33 The only current international requirement for proof of vaccination is yellow fever. Many countries, including Australia, require persons entering within a short time of visiting a yellow fever endemic area to have a valid yellow fever vaccination certificate. Paragraphs 2.23 to 2.26 refer. The World Health Organisation (WHO) publication: *International Travel and Health* (http://www.who.int/ith/en/) lists countries endemic for yellow fever and countries requiring yellow fever vaccination for travellers coming from endemic countries. However requirements can change at short notice. Current information is available from the Australian Disease and Environmental Alert Reporting System (http://intranet.defence.gov.au/vcdf/sites/ASDEARS/ComWeb.asp?page=38893).

4.34 Some countries do not require proof of yellow fever vaccination in the case of infants under one year.

4.35 If the vaccinator is of the opinion that medical grounds exist for withholding yellow fever vaccination, the circumstances are to be referred to a Senior Medical Officer (SMO) for review and direction. The Handbook provides additional information. A letter stating that vaccination is contra-indicated should be written on letterhead stationery and bear the stamp of an approved yellow fever vaccination provider. It is stressed that such recommendations are not necessarily accepted by health authorities enroute, or in destination countries, and that such persons may be subject to quarantine or surveillance.

MEMBERS PROCEEDING OVERSEAS

4.36 Members proceeding overseas are to be vaccinated in accordance with the requirements set out in this manual and for their country of destination. All members are to be in possession of their correctly completed Web Form PM 135—International Certificates of Vaccination or Prophylaxis (http://intranet.defence.gov.au/webforms/form?pm135).

4.37 The ADF sometimes requires members to depart overseas at short notice, leading to potential problems with regard to completion of some additional vaccinations.
THIRD COUNTRY DEPLOYMENTS

4.38 Defence third country deployment (TCD) personnel (that is Australian personnel serving with another force) who are to deploy, or are serving in an Australian Area of Operations are to have any additional vaccinations in accordance with the ADF Health Support Order for the deployment. Where no Health Support Order for a TCD exists, Strategic Operations Division consultation with SGADF is to occur. When a foreign unit with whom a Defence member is serving requires that Defence TCD personnel undergo additional vaccinations beyond the standard vaccinations prescribed in this manual, these vaccinations are subject to SGADF approval.

4.39

DEPENDANTS OF MEMBERS AND AUTHORISED CIVILIANS PROCEEDING OVERSEAS

4.40 Dependants of Defence members and authorised civilians proceeding outside Australia at Commonwealth expense other than on operations and exercises must also comply with the health and vaccination requirements appropriate for the country they are travelling to. Vaccinations and medical examinations can be obtained through recognised civilian organisations eg The Travel Doctor. Referrals to these agencies will be made by a Defence health facility for dependants and Defence civilians going in support of an operation or exercise and by the Overseas Administration Cell for Defence civilian employees and their families. Accounts issued for these preparations will be cost captured against the code on a serving member’s Posting Order or against the Mounting Order which identifies the particular operation or exercise the authorised civilian is to deploy on. Contractors will incur the cost for the above themselves. Philanthropic organisations will be provided with all pre-deployment health preparations at a Defence health facility. This is covered in more detail in HD 927—Defence Health Support to Civilians Proceeding Overseas (http://intranet.defence.gov.au/home/documents/data/ADFPUBS/HPD/hd927.pdf).

4.41 Any vaccinations that have been given should have been recorded in each individual’s International Certificate of Vaccination (ICV). Individual ICV are required for each dependant travelling overseas.
CHAPTER 5
VACCINATIONS AGAINST BIOLOGICAL WARFARE AGENTS

Introduction

5.1 The organisms that cause many naturally-occurring diseases could be weaponised and used as biological warfare (BW) agents.

5.2 Influenza, Japanese encephalitis, Q fever and yellow fever vaccines are registered by the Therapeutic Goods Administration, and detailed information is provided in the Product Information and the Australian Immunisation Handbook (the Handbook) (http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home). Smallpox vaccine is also registered in Australia but not for prophylaxis against biological warfare threat. Anthrax and botulinum toxoid vaccine are not registered in Australia. The use of these unregistered vaccines must be used in accordance with legal and procedural constraints. The off-label use of Smallpox vaccine also requires the informed consent of the recipient. Australian Defence Health Research Ethics Committee approved briefing material and consent forms are provided in the annexes to this chapter.

Unregistered vaccines

5.3 The procedures to be followed when an unregistered vaccine is to be used in Defence members are contained in Garrison Health Instruction 7.3.0.1—Use of unregistered therapeutic substances and medical devices in the ADF (http://intranet.defence.gov.au/vcdf/sites/JHCHIs/comweb.asp?page=87118&Title=7)

5.4 Director Health Materiel, Logistics and Pharmacy (DHMLP) is the point of contact for the list of ADF medical officers who hold a delegation to approve importation, exportation, supply and use of unregistered therapeutic goods under paragraph 19(1)(a) of the Therapeutic Goods Act 1989 (http://www.comlaw.gov.au/Details/C2013C00132).
5.5 The use of unregistered vaccines must be reported in accordance with Garrison Health Instruction 7.3.0.1. Adverse events following immunisation are to be reported in the usual way, in accordance with Health Bulletin (HB) 1/2010—Adverse drug reaction reporting (http://intranet.defence.gov.au/home/documents/DATA/ADFPUBS/DHB/HB01_10.PDF).

Related policy

5.6 Other related policy can be found in the following:


Annexes:
A. Example—Anthrax immunisation consent form and information sheet
B. Example—Botulinum Toxoid Vaccine consent form and information sheet
C. Example—Smallpox immunisation consent form and information sheet
EXAMPLE—ANTHRAX IMMUNISATION CONSENT FORM AND INFORMATION SHEET

CONSENT FORM FOR ADMINISTRATION OF ANTHRAX VACCINE

I, ..............................................

(full name)

hereby consent/do not consent* to the administration of Anthrax vaccine for myself.

(* Strike out whichever is not applicable)

In addition I confirm that:

• I understand that this product is not registered by the Therapeutic Goods Administration for sale in Australia but it has been approved for importation;

• I have read the information provided on pages 2–4, relating to the use of Anthrax vaccine and have understood the information presented;

• I have discussed the use of the above with the medical officer and been given the opportunity to ask questions;

• I understand that I may refuse to accept Anthrax vaccine without prejudicing my medical care but that I may not be eligible for specific operational deployments;

• I understand that in accepting Anthrax vaccine I do so without prejudicing my right to future medical care and military compensation entitlements; and I have signed this form in the presence of an Australian Defence Force (ADF) Health Care professional.

Signed: .............................................. Date: ................

I confirm that I have discussed the relevant products with the above named.

Signed: .............................................. Date: ................

Printed Name: ..............................................

Position/Designation: ..............................................
ANTHRAX IMMUNISATION INFORMATION SHEET

WHAT IS ANTHRAX?
1. Anthrax is a serious illness caused by the bacterium, Bacillus anthracis. It is primarily a disease of plant-eating animals—cattle and sheep being common hosts. Human infection with anthrax can result in death, even with the best available treatment.

2. Anthrax is not a new disease, having been recorded from around 1500 BC. During the 1930s, extensive research was conducted in Germany, Russia, and Japan toward the use of anthrax as a biological weapon. During World War II, several countries produced anthrax, yet Japan was the only country to use it as a biological warfare agent. Since 1945 several countries have developed anthrax as a biological weapon, including the former Soviet Union and Iraq.

HOW IS IT SPREAD?
3. Human infection with anthrax can be caused by direct contact with products from infected animals (hides, hair or wool), eating infected meat or inhaling anthrax spores. Natural infection through direct contact or ingestion is very uncommon due to widespread measures to control the disease. The greatest threat from anthrax for Defence members is inhalation of aerosol spores produced as a biological warfare agent.

WHAT HAPPENS TO PEOPLE WHO ARE INFECTED WITH ANTHRAX?
4. There are two main forms of anthrax, cutaneous (skin) and inhalation, based on route of entry to the body. The incubation period for anthrax is usually 1 to 7 days, with most cases occurring within 2 days of exposure. The incubation period for inhalational anthrax has been recorded up to 60 days. Inhalational anthrax results in death in 90–100% of cases.

5. The first symptoms of inhalation anthrax are flu-like symptoms such as sore throat, mild fever, chest pain, cough and muscular pain. Within 2 to 3 days, serious breathing difficulties, collapse and shock develop. Death occurs within 24 to 36 hours of development of these serious symptoms.

CAN PEOPLE WITH INHALATION ANTHRAX BE TREATED?
6. After exposure to anthrax, treatment with antibiotics may be effective in preventing disease if it is begun before the onset of any symptoms. To be optimally effective, preventive treatment should be started within hours of exposure. As aerosol spores are invisible, tasteless and odourless, personnel may be exposed without their knowledge. Once symptoms have started, the efficacy of antibiotic treatment is very poor. If not treated immediately and aggressively in a state-of-art hospital centre, once severe symptoms develop, 45% to 80% of patients will die.

DO INFECTED PERSONS SPREAD THE DISEASE TO OTHERS?
7. Anthrax is not spread from person to person.

WHY IS ANTHRAX AN EFFECTIVE BIOLOGICAL WARFARE AGENT?
8. Anthrax bacteria are capable of forming spores, which are thick walled inactive forms. Bacterial spores may survive quite extraordinary extremes of temperature, dehydration or chemical insult. Spores are easily stored and remain dangerous for a long period.

9. Anthrax spores are well suited for delivery by missiles or bombs. They can also be dispersed by small devices using explosives, generators that use either explosives or compressed air, or spray devices. Anthrax would most likely be dispersed in aerosol form.

HOW CAN ANTHRAX INFECTION BE PREVENTED?
10. The single best way to protect against many life-threatening diseases is via vaccination. Vaccines work by stimulating the human body’s natural defences to prevent the development of a disease if later exposed to it.

IS THERE MORE THAN ONE TYPE ANTHRAX VACCINE?
HOW EFFECTIVE ARE THE VACCINES?
12. No vaccine provides 100% protection. However, the available evidence indicates that both types of vaccine provide equally effective protection against anthrax.

HOW QUICKLY DO THE VACCINES PROVIDE PROTECTION?
13. Both vaccines provide some protection after the second injection and good protection after the third injection (i.e., after four or six weeks). If you are exposed to anthrax before you have had your third dose, you may be given antibiotic treatment.

HOW LONG DOES PROTECTION PROVIDED BY ANTHRAX VACCINES LAST?
14. In order to maintain immunity, personnel require a booster vaccine dose each year after completion of the primary schedule. The primary schedules are complete at the 18 month injection.

WHAT HAPPENS IF I HAVE ALREADY HAD SOME VACCINE DOSES?
15. You must complete the primary schedule for your vaccine type. If a longer interval than that recommended in the schedule has elapsed since your last dose, you should resume the schedule, extending the times according to the schedule. Additional doses to compensate for any delay are not required.

CAN I GET ANTHRAX INFECTION FROM VACCINATION?
16. Neither type of anthrax vaccine contains live bacteria. Therefore, they do not introduce any form of anthrax infection.

WHAT ARE THE POSSIBLE ADVERSE EFFECTS OF THE VACCINES?
17. Local reactions. Reactions at the injection site usually last from one to three days and go away without treatment. Redness, itching, and/or swelling, occurs in up to one third of men and up to two thirds of women following anthrax vaccination. Such reactions are usually only small but in rare cases may be up to 13 centimetres in diameter. Soreness or local pain occurs in up to one fifth of persons vaccinated. A lump at the injection site is common, occurring in up to 90% of people vaccinated. The lump may persist for a few weeks.

18. Systemic reactions. Reactions away from the injection site occur in up to one third of people vaccinated. These reactions may include muscle aches, joint aches, chills, low-grade fever, decreased appetite, headaches, nausea, and swollen glands. They usually go away in a few days.

19. Acute allergic reactions. These reactions, which may be severe, are very rare (about 1 in 100,000) but may occur with anthrax vaccines, as with any vaccine. There is no evidence that other types of serious reactions occur with either type of anthrax vaccine.

WHAT DO I DO IF I EXPERIENCE ADVERSE EFFECTS?
20. You should avoid strenuous exercise for at least 48 hours following local or systemic reactions. You should report to your ADF Health Care professional for further advice. Treatment will not usually be required. It is very unlikely that you will not be able to complete the schedule.

IS THERE ANY RISK OF CANCER OR MUTAGENESIS (GENETIC MUTATIONS)?
21. In nearly 30 years of use, there is no evidence that Anthrax vaccines cause cancer or mutagenesis. As with most other vaccines, or other pharmaceuticals, studies regarding carcinogenesis or mutagenesis have not been performed with Anthrax vaccine. Such studies have not been performed, in large part, because in over 200 years, of administering vaccines to humans, no vaccine has ever been shown to cause cancer or genetic mutations.

WHO SHOULD NOT HAVE ANTHRAX VACCINATION?
22. The following should not have anthrax vaccine at all:
   a. Persons who have had an acute allergic reaction to a previous dose of anthrax vaccine or to any of the vaccine’s components.
   b. Persons younger than 18 or older than 65.
   c. Persons who are HIV positive.

23. Vaccination should be temporarily deferred in the following circumstances:
   a. Pregnancy, suspected pregnancy.
b. Women who are breast feeding.

c. Active infection/illness with fever.

d. Depressed immune response, including corticosteroid or other immuno-suppressive treatment.

IS THE VACCINE COMPULSORY? WHAT HAPPENS IF I DON’T HAVE IT?

24. Anthrax vaccination is not compulsory. However, if the Health Support Plan for a particular operation indicates that Anthrax vaccination is a requirement, personnel who decline vaccination may not be considered eligible for deployment to that operation.

ARE ANTIBIOTICS AN ALTERNATIVE TO VACCINATION FOR PREVENTION OF ANTHRAX?

25. No. Long-term antibiotic treatment is not an acceptable alternative to vaccination because it is less effective in preventing infection and has unacceptable side effects.

ONCE I HAVE BEEN VACCINATED, DO I NEED TO DO ANYTHING ELSE TO PROTECT MYSELF AFTER EXPOSURE TO ANTHRAX?

26. Even when fully immunised, antibiotics may be still indicated after aerosol exposure, to achieve survival as close to 100% survival as possible.

WHERE CAN I GET FURTHER INFORMATION?

27. Ask your Defence health care professional, as there is a great deal of information available.
CONSENT FORM FOR ADMINISTRATION OF BOTULINUM VACCINE

I, .................................................................

(full name)

hereby consent/do not consent* to the administration of botulinum vaccine for myself.

In addition I confirm that:

• I understand that this product is not registered by the Therapeutic Goods Administration for sale in Australia but it has been approved for importation;

• I have read the information provided on pages 2–4, relating to the use of botulinum vaccine and have understood the information presented;

• I have discussed the use of the above with the medical officer and been given the opportunity to ask questions;

• I understand that I may refuse to accept botulinum vaccine without prejudicing my medical care but that I may then not be eligible for specific operational deployments;

• I understand that, in accepting botulinum vaccine, I do so without prejudicing my right to future medical care and military compensation entitlements; and I have signed this form in the presence of an Australian Defence Force health care professional.

Signed: ..............................................  Date: ................

I confirm that I have discussed the relevant products with the above named.

Signed: ..............................................  Date: ................

Printed Name: ..................................................

Position/Designation: ..................................................
WHAT IS BOTULINUM TOXIN POISONING (BOTULISM)?
1. Botulinum toxin has been developed as a biological weapon and an aerosol attack is considered the most likely way in which this colourless, odourless and tasteless agent would be used.

2. Botulinum toxin poisoning (Botulism) is a paralysing illness caused by nerve toxin produced by Clostridium botulinum bacteria. This toxin is the most potent and lethal toxin known. It affects the nervous system by stopping signals from the brain getting to the muscles. Death from botulinum toxin poisoning generally occurs through breathing failure. Botulism is not spread from person to person and the three main natural forms of the disease are:
   a. food borne botulism, which occurs when a person consumes improperly processed foodstuffs containing preformed toxin produced by the bacteria;
   b. infant botulism, which occurs in a small number of susceptible infants who harbour the bacteria in their intestinal tract; and
   c. wound botulism, which occurs when wounds are contaminated by the toxin-producing bacteria.

CAN BOTULINUM TOXIN POISONING BE SPREAD FROM PERSON TO PERSON?
3. Botulinum toxin poisoning is not spread from one person to another.

HOW DOES BOTULINUM TOXIN AFFECT HUMANS?
4. The toxin destroys the nerves that enable people to breath and swallow, so, without ventilators and intensive life support, victims almost always die.

WHAT ARE THE SYMPTOMS OF BOTULINUM POISONING?
5. Symptoms of inhalational botulinum toxin poisoning may begin as early as 24–36 hours following exposure, or as late as several days. The classic symptoms of botulinum toxin poisoning include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth, and muscle weakness. These are all symptoms of the muscle paralysis caused by the bacterial toxin. If untreated, these symptoms may progress to paralysis of the arms, legs, trunk and respiratory muscles. In food borne botulinum toxin poisoning, symptoms generally begin 18 to 36 hours after eating a contaminated food, but they can occur as early as six hours or as late as 10 days.

HOW IS BOTULISM TREATED?
6. Antibiotics have no known direct effect on botulism. Therapy for botulism consists of supportive care including prompt respiratory support for breathing failure and the timely administration of the equine (horse derived) antitoxin. Early administration of botulinum antitoxin is critical to minimise the effects of the toxin.

HOW EFFECTIVE IS THE ANTITOXIN?
7. Botulinum antitoxin decreases the progressive nerve damage and disease severity, but does not reverse existing paralysis. Intensive and prolonged nursing care may be required for recovery, as it may take anywhere from three to 12 months for the nerves to regrow and for the body to recover completely. Patients who survive an episode of botulinum toxin poisoning may have fatigue and shortness of breath for years and long-term therapy may be needed to aid recovery.

WHAT IS BOTULINUM VACCINE?
8. Botulinum vaccine is a vaccine that protects against A, B, C, D and E types of botulism and is available from the Centers for Disease Control and Prevention (CDC) in the United States of America. This product has been administered to several thousand volunteers and occupationally at-risk workers and induces antitoxin levels that correspond to protective levels in experimental animals.

WHAT ARE THE SIDE EFFECTS OF THE VACCINE?
9. Mild reactions (ie. redness, swelling and hardening at the injection site) occur in two per cent to four per cent of recipients on initial vaccination, and in up to 20 per cent of recipients after booster doses. These types of reactions should be gone within 48 hours.

10. Moderate reactions (ie. pain and soreness at the injection site, fever, tiredness, headache, rashes and muscle pain, as well as those symptoms associated with mild reactions) occur in up to
three per cent of recipients. All such reactions reach a peak in 24 hours, then gradually subside and should be gone at 48 or, at the most, 72 hours.

11. Severe incapacitating reactions are very uncommon (ie. 0.04 per cent) and these usually resolve within three to four weeks.

WILL THE SIDE EFFECTS I EXPERIENCE BE RECORDED?

12. It is a requirement of the CDC that all side effects experienced be recorded on the CDC Form 519.7—Response to Investigational New Drug. A copy of this form will be placed on your medical file.

CAN I GET BOTULINUM TOXIN POISONING FROM THE VACCINE?

13. The vaccine does not contain any live bacteria. The vaccine does contain toxoid derived from inactivated, partially purified toxin types A, B, C, D and E. The toxoid in the vaccine cannot cause botulimum toxin poisoning.

CAN ANY AUSTRALIAN DEFENCE FORCE HEALTH OFFICER ADMINISTER THE BOTULINUM VACCINE?

14. No. Because the CDC lists this as an Investigational New Drug, only doctors registered with the CDC as clinical investigators, or doctors under supervision of registered clinical investigators, may administer the vaccine.

HOW MANY INJECTIONS WILL I NEED?

15. Initial vaccination is a course of three injections given at weeks 0, 2, 12. Shortly after the third injection, personnel will have maximum protection against botulimum toxin poisoning. The first booster injection is given at 12 months after the initial injection. From thereon booster injections are administered once every two years, and only if tests show that antibody levels are sufficiently low as to require the booster.

ARE THERE ANY FOLLOW UP HEALTH CHECKS?

16. Yes. A 48-hour post vaccine arm examination is required following each injection.

WHY DO I HAVE TO SIGN A CONSENT FORM?

17. It is a requirement of the CDC, who supply the vaccine to the ADF via the Australian Therapeutic Goods Administration, that all people who receive the vaccine sign a consent form.

WHO SHOULD NOT BE VACCINATED?

18. The vaccine should only be administered to healthy men and women, between the ages of 18 and 65 years, since investigations so far have only been conducted on people within this age bracket. The effects of administration of the vaccine on women who are pregnant have not been studied and therefore it should not be given to anyone who is, or might be, pregnant. No one should be administered a second or subsequent booster injection, unless laboratory tests have shown antitoxin type B and/or E to be below satisfactory levels.

FOR HOW LONG DOES THE VACCINE PROVIDE PROTECTION AGAINST BOTULINUM TOXINS?

19. The primary schedule doses are given at 0, 2 and 12 weeks. Full protection occurs after the third injection and lasts for one year. The fourth injection will then provide protection for approximately two years before tests are needed to determine if, and when, further booster shots will be required. The number and timing of booster injections may vary from person to person.

WHERE CAN I GET FURTHER INFORMATION?

20. Ask your ADF health care professional, as there is additional information available.
ANNEX 5C
EXAMPLE—SMALLPOX IMMUNISATION CONSENT FORM
AND INFORMATION SHEET

SMALLPOX VACCINATING CONSENT FORM

I, ______________________________________________________

(full name)

hereby consent/do not consent* to the administration of Smallpox vaccine for myself.

(*Strike out whichever is not applicable)

In addition I confirm that:

- I understand that this product is not currently registered by the Therapeutic Goods Administration for sale in Australia but it has been approved for importation;
- I have received, read and understood the information provided on pages 2–4 on Smallpox vaccine. I understand the indications to receive vaccination against smallpox;
- I understand the contraindications and adverse events relating to smallpox vaccination;
- I have had the opportunity to discuss my medical concerns with an Australian Defence Force Healthcare professional;
- I understand that I may refuse to accept Smallpox vaccine without prejudicing my medical care but that I may not be eligible for specific operational deployments;
- I understand that in accepting Smallpox vaccine I do so without prejudicing my right to future medical care and military compensation entitlements; and
- I have signed this form in the presence of an Australian Defence Force Health Care professional.

Signed: ___________________________ Date: __________

I confirm that I have discussed the relevant products with the above named.

Signed: ___________________________ Date: __________

Printed Name: ________________________________

Position/Designation: ________________________________
WHAT IS SMALLPOX?

21. Smallpox is a serious, contagious, and sometimes fatal infectious disease caused by the variola virus. There is no specific treatment for smallpox disease, and the only prevention is vaccination.

22. A smallpox outbreak could cause many casualties among unvaccinated troops, disrupting a unit’s ability to perform its mission effectively and creating a huge logistics burden.

23. Vaccines provide a safe and effective means of countering the threats to personal health and operational readiness.

24. Except for laboratory stockpiles, smallpox has been eliminated around the world. However, in the aftermath of the events of September and October 2001, there is heightened concern that the variola virus might be used as an agent of biological warfare or bioterrorism.

HOW IS SMALLPOX SPREAD?

25. Generally, direct and fairly prolonged face-to-face contact is required to spread smallpox from one person to another, however, it can also be spread through direct contact with infected bodily fluids or contaminated objects such as bedding or clothing. Rarely, smallpox has been spread by virus carried in the air in enclosed settings such as buildings, buses, and trains.

WHAT HAPPENS TO PEOPLE WHO ARE INFECTED WITH SMALLPOX?

26. Exposure to the virus is followed by an incubation period of 7–19 days where people feel fine. During this time, people are not contagious.

27. The first symptoms (duration: two–four days) include fever, malaise, head and body aches, vomiting and a high fever. This phase may be contagious.

28. During the most contagious phase (duration: about four days) a rash emerges first as small red spots on the tongue and in the mouth. The spots develop into sores that erupt and spread large amounts of the virus into the mouth and throat. Raised, pus-filled bumps (similar to chicken pox) develop over the entire body within 24 hours, which will eventually crust and form scabs.

29. The infected person may remain contagious until the last smallpox scab falls off. Each smallpox scab may leave a scar which will remain for life.

CAN PEOPLE WITH SMALLPOX BE TREATED?

30. There are currently no specific therapies with proven effectiveness to treat smallpox although research into anti-viral agents is continuing. Medical care of more seriously ill patients consists of supportive measures only.

WHY IS SMALLPOX AN EFFECTIVE BIOLOGICAL WARFARE AGENT?

31. A deliberate reintroduction of smallpox as an epidemic disease would be devastating. If the variola virus were adapted for use in bombs or missiles, an aerosol release would result in many casualties among unvaccinated troops, disrupting a unit’s ability to perform its mission effectively.

HOW CAN SMALLPOX BE PREVENTED

32. The single best way to protect against many life-threatening diseases is via vaccination. Vaccines work by stimulating the human body’s natural defences to prevent the development of a disease if later exposed.

WHAT IS SMALLPOX VACCINE?

33. Smallpox vaccine is made from a virus called vaccinia, which is a ‘pox’-type virus related to smallpox. The smallpox vaccine contains the ‘live’ vaccinia virus. The vaccine does not contain the smallpox virus and cannot give you smallpox.

34. Although Smallpox vaccine is approved for use in its country of manufacture, the Therapeutic Goods Administration (TGA) has not registered it for general use in Australia. TGA has, however, approved the importation. This is not to imply that the vaccine is unsafe. The only reason that it is not registered is because of economic considerations. It costs many millions of dollars to have a vaccine approved, and as such, no Australian company believes they can make a profit from it, due to low demand.
HOW EFFECTIVE ARE THE VACCINES?

35. No vaccine provides 100 per cent protection. However, the available evidence indicates 95% immunity following smallpox vaccine, which lasts seven–ten years.

RISKS ASSOCIATED WITH SMALLPOX VACCINE?

36. There are side effects and risks associated with the smallpox vaccine as there are with any medication.

37. The risk of smallpox vaccine causing serious harm is very small. Most people experience normal, usually mild reactions that include a sore arm, fever, and body aches. However, some people may be at risk of smallpox vaccine complications and should not receive this vaccine.

38. You are at risk if you:
   a. have a current or past history of skin conditions, particularly a history of eczema or allergic dermatitis, or other active skin conditions;
   b. have a weakened immune system, such as following an organ transplant, in conditions such as lupus, following cancer treatment (radiotherapy and/or chemotherapy), or with HIV infection;
   c. are taking steroids for inflammatory conditions, particularly of the eye;
   d. have ever had a life threatening allergic reaction to polymyxin B, streptomycin, chlortetracycline, or neomycin;
   e. are pregnant or breast feeding;
   f. have known heart disease including:
      (1) previous heart attack;
      (2) chest pain caused by lack of blood flow to the heart;
      (3) congestive heart failure;
      (4) cardiomyopathy (heart muscle becomes inflamed and doesn’t work as well as it should);
      (5) stroke or mini-strokes (strokes that produce stroke-like symptoms but no lasting damage);
      (6) chest pain or shortness of breath with activity; or
      (7) other heart conditions under the care of a doctor.
   g. Have three or more cardiac risk factors from the following conditions:
      (1) high blood pressure;
      (2) high cholesterol;
      (3) Diabetes;
      (4) a family history of heart disease; or
      (5) currently smoke cigarettes.

Note

As the vaccine contains live organisms, close personal contact with anyone who has any of the above conditions must be strictly avoided following vaccination until the last scab has dried and fallen off (up to three weeks).
EFFECTS OF THE VACCINE?

39. Normal, typically mild reactions (usually go away without treatment) include:
   a. the arm receiving the vaccination may be sore and red where the vaccine was given;
   b. the glands in the armpits may become large and sore;
   c. headache, fatigue, mild rash, muscle aches, pains or chills may develop eight to 12 days after vaccination; or
   d. one out of three people may feel bad enough to miss work, school, or recreational activity or have trouble sleeping.

40. Moderate reactions. In the past, about 1:1000 people vaccinated for the first time experienced reactions that, while not life-threatening, were serious and may require medical attention. If you develop any of the following signs or symptoms post vaccination, please seek immediate assistance from your nearest medical facility:
   a. high fever,
   b. behaviour changes,
   c. severe rash over entire body, or
   d. a reaction that spreads from the vaccination site and doesn’t get better.

41. Severe reactions. Rarely, people have had very severe and life threatening reactions to the vaccine. Urgent assistance and treatment is required if the following symptoms develop:
   a. difficulty breathing;
   b. hoarseness or wheezing;
   c. widespread skin rash (or other skin changes);
   d. severe headaches;
   e. weakness, dizziness; or
   f. rapid heart rate.

IS THE VACCINE COMPULSORY?

42. Smallpox vaccination is not compulsory. However, if the Joint Health Support Agency Health Support Plan for a particular operation indicates that smallpox vaccination is a requirement, personnel who decline vaccination may not be considered eligible for deployment to that operation.

WHERE CAN I GET FURTHER INFORMATION?

43. Further fact sheets with more in depth information on smallpox are available at the medical facility.
CHAPTER 6
IMMUNISATION DATA IN ELECTRONIC HEALTH RECORDS
RESERVED
CHAPTER 7

STORAGE

Storage of biological products

7.1 Proper storage is essential if biological products are to retain their potency for a reasonable period. Storage conditions, as specified by the manufacturer, are to be followed at all times. Failure to observe proper storage conditions may result in serious deterioration of the product, with consequent loss of:

a. potency,

b. activity, or

c. antigenicity.

7.2 The factors, which must be strictly controlled, are:

a. temperature,

b. light, and

c. humidity.


7.4 Vaccines required to be frozen should be stored below freezing point. All other vaccines are to be stored between two and eight degrees Celsius, in approved drug fridges. They must never be placed in the freezer compartment. Vaccines that are required to be stored between two and eight degrees Celsius, and which have been inadvertently frozen, are to be discarded. In the case of an emergency where a domestic fridge has to be used for temporary storage of vaccines, a thermometer which will record both the maximum and minimum temperatures reached during any nominated period should be used. The following thermometer, catalogued as 6685–66–150–8606, is available: Thermometer, Recording, Digital, for Drug Refrigerator Temperature Monitoring.

7.5 Effect of light. All biological products must be protected from direct sunlight. Some living vaccines will be inactivated very rapidly, and the activity of other preparations will be seriously affected if exposed to sunlight for any length of time.
7.6 **Effects of humidity.** Changes in relative humidity will not affect products that are hermetically sealed in ampoules or bottles. However, excessively humid conditions have a deleterious effect on tablets unless airtight sealing of the container is maintained.

7.7 **Transport.** Insulated containers with cold chain monitors should be used for transport. The handbook and national vaccine storage guidelines provide guidance on the use of these monitors. Although it is not always possible to achieve ideal conditions for storage of biologicals during transport, every effort should be made to keep these products at temperatures as close as possible to those recommended at all times. Upon receipt of biological products the in transit temperatures are to be checked prior to usage. Exposure to direct sunlight must be avoided at all times during transportation and cool, dark places should be selected for storage.

7.8 Biological products that must be maintained in a frozen state are to be discarded if they are received in a thawed state.
CHAPTER 8

ANTIVENOMS

Introduction

8.1 An antivenom is a preparation which contains purified antibodies against venoms or venom components. Antivenoms are used to neutralise systemic envenomation caused by the venoms (poisons) transmitted to humans by the bites or stings of arthropods, marine animals and snakes. (An earlier term, which is now obsolete, although it is still used occasionally, was ‘antivenene’. The term ‘antivenom’ is now the standard, and preferred, term). Arthropods include insects (bees, wasps and ants), arachnids (spiders, ticks and scorpions) and centipedes. Marine animals for which antivenoms exist are the Stonefish and the Box Jellyfish (Chironex fleckeri).

8.2 For detailed clinical and technical information on the use of antivenoms, the following publications are available on the Clinical Toxinology Resources website (http://www.toxinology.com), or under ‘Antivenoms’ at the Commonwealth Serum Laboratories (CSL) Biosciences website (http://www.csl.com.au):

a. CSL Antivenom Handbook© (2001), Julian White (CSL Ltd), ISBN 0 646 26814 7; (http://www.toxinology.com/generic_static_files/cslavh_svdk.html); and


8.3 These publications are also available as hard copy handbooks from:

CSL Biosciences
45 Poplar Street
PARKVILLE VIC 3052
Australia
Telephone: 61 3 9389 1000, or toll free 1800 032 675
Facsimile: 61 3 9389 1646
Email: customer.service@csl.com.au

CSL Biosciences website (http://www.csl.com.au/contact-csl)


8.5 Information may also be obtained from the Australian Venom Research Unit (AVRU) website (http://www.avru.org/).

8.6 Contact details for specialist advice. Contact details for specialist advice on any envenomation issues are:
a. National Poisons Information Line:
   Telephone: 13 11 26

b. Toxinology Department, Women’s and Children’s Hospital, North Adelaide:
   Telephone: 61 8 8161 7000 or 1300 760 451
   Facsimile: 61 8 81616049
   Email: toxinaus@wch.sa.gov.au

c. Australian Venom Research Unit:
   Telephone: 61 3 8344 7753
   Facsimile: 61 3 9348 2048
   Email: mail@avru.org

ANTIVENOM TYPES AND DOSAGES

Snake antivenoms

8.7 Signs and symptoms of envenomation from Australian snakes are discussed in detail in the CSL Antivenom Handbook (http://www.toxinology.com/generic_static_files/cslavh_svdk.html) (see paragraph 8.2). Envenomation syndromes vary according to the type of snake, and may include paralysis, defibrination coagulopathy, myolysis and major renal damage in severe cases.

8.8 There are about 100 species of snake in Australia, of which about twenty are dangerous or potentially dangerous to humans. These are the snakes for which antivenoms have been developed, as shown below. There are six types of monovalent antivenom used to treat snakebite envenomation in Australia, all of which are produced by CSL in Australia, namely:

a. CSL Black Snake Antivenom;

b. CSL Brown Snake Antivenom;

c. CSL Taipan Antivenom;

d. CSL Death Adder Antivenom;

e. CSL Tiger Snake Antivenom; and

f. CSL Sea Snake Antivenom.

8.9 There is also CSL Polyvalent Snake Antivenom, each vial of which contains the equivalent of one vial of each of the five monovalent snake antivenoms. It should not be used if it is possible to use a specific, monovalent snake antivenom. CSL Polyvalent Antivenom is used when:

a. the identity of the venom has not been determined; or

b. the patient is severely envenomated and administration of antivenom cannot be delayed until the results of the CSL Snake Venom Detection Kit (SVDK) (http://www.csl.com.au/docs/790/106/03100000F%20SVDK%20Product%20
Leaflet test are obtained (in this case urine or blood samples must be taken before antivenom is administered); or

c. no specific, monovalent antivenom is available for the type of snake involved.

8.10 The choice of snake antivenoms depends on whether the type of venom has been identified. If the venom has been positively identified, the specific antivenom for that snake should be used. Visual identification of snakes, even by medical or paramedical personnel, is notoriously unreliable and could lead to a fatality in the event of misidentification. Only expert, fully trained herpetologists can correctly identify snakes. It is not necessary to catch the snake in order to identify the venom.

8.11 Commonwealh Serum Laboratories Snake Venom Detection Kit (CSL SVDK). The CSL SVDK is used to identify the venom; these results are used in conjunction with the clinical history to determine the treatment. For detailed instructions on the use of the CSL SVDK, see CSL publication Snake Venom Detection Kit Technical Information (refer paragraph 8.2 for access details). The CSL SVDK is a rapid bioassay. The CSL SVDK detects the presence of venom and indicates which of the types of antivenom should be used. Sea Snake venom is not detected by the CSL SVDK, although it may yield a positive result, probably with a primary positive result in the Tiger Snake section of the CSL SVDK.

8.12 Details of how to use the CSL SVDK are contained in the Product Information leaflet, in the CSL SVDK Technical Information, and in HLTHMAN volume 22. The kit comprises vials of yellow sample diluent, chromogen and peroxide, cotton swabs, test strips, and a strip holder. In summary the procedure involves:

a. taking a swab from the bite site,
b. preparing the test strip,
c. adding the test sample,
d. removing the well contents,
e. washing the test wells,
f. adding chromogen reagent to each of the test wells,
g. adding peroxide reagent to each of the test wells, and
h. interpreting the results.

8.13 In some cases the bite site may not be identifiable, or it may have been washed, in which case an alternative sample needs to be taken. Sometimes a venom sample can be obtained from affected areas of the clothing or bandage. Urine or blood may also be used if necessary. The test can detect very small quantities of venom.

8.14 Interpretation of CSL SVDK results involves noting which of the wells undergoes a colour change (to blue). For the test to be valid, well 6 (the control well) must remain colourless, or nearly so, and well 7 (the positive control well) must be blue at the end of 10 minutes testing. Table 8-1 gives a summary of how results are
interpreted. Little information is available on reactions of the venoms of the less common snake species, e.g., Whip Snakes.

**Table 8-1: Interpretation of Commonwealth Serum Laboratories Snake Venom Detection Kit results**

<table>
<thead>
<tr>
<th>Well</th>
<th>Colour</th>
<th>Type of venom detected</th>
<th>Antivenom recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Blue</td>
<td>Tiger Snakes and Black Tiger Snakes (<em>Notechis</em> species), or Copperhead (<em>Australeps</em> species), or Rough-scaled or Clarence River Snake (<em>Topidechis carinatus</em>).</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>NOTE:</strong> On occasion bites by the following species may give positive results in Well 1: <em>Hoplocephalus</em> species (Broad-headed Snake, Pale-headed Snake, Stephen’s Banded Snake)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Blue</td>
<td>Brown Snakes (<em>Pseudonaja</em> species), including Eastern Brown Snake, Gwardar (Western Brown Snake), Dugite, Speckled Brown Snake, Ingram’s Brown Snake and others.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CSL Brown Snake Antivenom</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Blue</td>
<td>Black Snakes (<em>Pseudechis</em> species), including: Mulga or King Brown Snake or Collett’s Snake. Also can be used for Red-bellied Black Snake or Blue-bellied Black Snake (Spotted Black Snake), but envenomation from these species can be treated with CSL Tiger Snake Antivenom</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CSL Black Snake Antivenom</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Blue</td>
<td>Death Adders (<em>Acanthophis</em> species)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CSL Death Adder Antivenom</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Blue</td>
<td>Taipans (<em>Oxyuranus</em> species), including: Common Taipan or Inland Taipan (Fierce Snake, Western Taipan) or Papuan Taipan</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CSL Taipan Antivenom</td>
<td></td>
</tr>
</tbody>
</table>

8.15 Due to natural cross-reactions between Australian elapid snake venoms, more than one of wells 1 to 5 may turn blue. The correct interpretation is to note the well that first turns blue. An example is Mulga Snake (*Pseudechis australis*) venom, which causes well 3 to turn blue but may also produce a partial blue colour in well 1.

8.16 A positive **CSL SVDK** result is not sufficient justification to commence antivenom treatment; clinical evidence of significant envenomation is required. Alternatively, a negative result from a CSL SVDK test does not justify withholding antivenom if the patient shows symptoms of systemic envenomation or abnormal pathology results indicating coagulopathy.

8.17 **Dosages of antivenoms.** Table 8-2 details dosages for snake antivenoms, based on those currently recommended by the **CSL Antivenom Handbook**, in
Australian Animal Toxins, and other published reports. Dosages for children and adults are the same.

**Table 8-2: Antivenom selection and dosage when venom and/or species have been positively identified**

<table>
<thead>
<tr>
<th>Antivenom Type</th>
<th>Snake Group</th>
<th>Units per vial</th>
<th>Dose (IV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSL Tiger Snake Antivenom</td>
<td>Genus <em>Notechis</em> Common (Mainland) Tiger Snakes—all species</td>
<td>3000 (=9–12 mL)</td>
<td>Minor bite 1–2 vials&lt;br&gt;Major to major bite 2–4+ vials</td>
</tr>
<tr>
<td></td>
<td><em>Notechis ater</em> Black Tiger Snakes—all subspecies from Tasmania, South Australia and WA, except Chappell Island Tiger Snake</td>
<td></td>
<td>Large specimens, starting dose 2–3 vials.</td>
</tr>
<tr>
<td></td>
<td><em>Notechis ater serventyi</em> Chappell Island Tiger Snake</td>
<td>4 vials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Genus <em>Australeps</em> Copperheads</td>
<td>1–3 vials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Genus <em>Tropidechis</em> Rough-scaled (Clarence River) Snake</td>
<td>1–3+ vials</td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Genus Pseudechis</em> Red-bellied Black Snake</td>
<td>1 vial. Two or more vials may be required in some cases.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blue-bellied Black Snake</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Genus <em>Hoplocephalus</em> Broad-headed Snake</td>
<td>1–3+ vials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pale-headed Snake</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stephen’s Banded Snake</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Genus <em>Pseudechis</em> All species of Brown Snake including:</td>
<td>1000 (=4.5–9 mL)</td>
<td>Minor bite 1–2 vials&lt;br&gt;Major bite with defibrination, initial dose 10 vials.</td>
</tr>
<tr>
<td></td>
<td>Eastern Brown Snake</td>
<td></td>
<td>Moderate bite 2–4 vials</td>
</tr>
<tr>
<td></td>
<td>Western Brown Snake (Gwardar)</td>
<td></td>
<td>In very severe cases, up to 20–30 vials have been reported to have been used in some cases in Western Australia (WA) and Queensland to manage</td>
</tr>
<tr>
<td></td>
<td>Dugite</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*FOI 186/16/17 Serial 3*
| CSL Black Snake Antivenom | Genus *Pseudechis* Mulga (King Brown) Snake  
|                           | Butler's Mulga Snake  
|                           | Papuan Black Snake  
|                           | Collett's Snake     | 18000 (=30–50 mL) | 1–3 vials, depending on severity. |
| Genus *Pseudechis*       | Red-bellied Black Snake  
|                           | Blue-bellied Black Snake  
|                           | Papuan Black Snake     | 18000 (=3–50 mL) | 1+ vials, depending on severity. Small-volume Tiger Snake Antivenom is preferable for Red-bellied Black Snake and Blue-bellied Black Snake. |
| CSL Taipan Antivenom     | Genus *Oxyuranus* Common Taipan  
|                           | Inland Taipan (Fierce Snake) | 12000 (=43–50 mL) | Minor bite 1–2 vials  
|                           |                                             |                     | Moderate to major bite, start with 2–3 vials but may need 4–6+ vials. |
| CSL Death Adder Antivenom| Genus *Acanthophis* All species of Death Adder | 6000 (=25–26 mL) | 1–3 vials, depending on the severity of the paralysis and the response to the antivenom. |
| CSL Polyvalent Snake Antivenom | All species of Australian venomous terrestrial (land) snakes | As above (45–60 mL) | Dosage should follow guidelines for monovalent antivenoms, as shown above. |
| CSL Sea Snake Antivenom  | All species of sea snakes | 1000 (=15–35 mL) | 1–3+ vials, depending on severity. Up to 10 vials have been used in severe cases. Do not use Tiger Snake Antivenom or Polyvalent Antivenom. |

8.18 If the patient is critically ill and administration of antivenom is necessary before the results of the CSL SVDK test are available or if the species of snake cannot be determined, use the antivenoms shown in Table 8-3.
Table 8-3: Antivenom selection and dosage where results of Snake Venom Detection Kit test are not known or species has NOT been determined

<table>
<thead>
<tr>
<th>State</th>
<th>Antivenom</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Victoria</td>
<td>CSL Brown Snake Antivenom AND CSL Tiger Snake Antivenom</td>
<td>Dosage should follow guidelines for monovalent antivenoms, as shown in Table 8–2.</td>
</tr>
<tr>
<td>Tasmania</td>
<td>CSL Tiger Snake Antivenom</td>
<td>Large specimens, starting dose 2–3 vials.</td>
</tr>
<tr>
<td>Other States and Territories</td>
<td>CSL Polyvalent Antivenom</td>
<td>Dosage should follow guidelines for monovalent antivenoms, as shown in Table 8–2.</td>
</tr>
</tbody>
</table>

8.19  **Snake antivenom administration.** For detailed information on the administration of snake antivenoms, refer to the CSL Antivenom Handbook and to Australian Animal Toxins.

8.20  **Snake antivenom** should be administered only by qualified medical or paramedical personnel unless in the most exceptional circumstances. If the patient is remote from medical aid, and there is no doubt that snake envenomation from a dangerous species has occurred and/or signs and symptoms of envenomation are present, then administration of antivenom via the IM route by a lay person may be justifiable in the most extreme and unusual life-threatening circumstances. However, this should only occur after radio consultation with an experienced medical officer. It can take up to 12 hours for 30–40 per cent of the injected antivenom to reach the circulation after IM injection. A very conservative approach should be adopted towards the use of snake antivenom in the field and it will almost invariably be better to transport the patient to a suitably-equipped medical centre before antivenom is administered. Field conditions are not ideal for antivenoms which should be stored in an environment with controlled temperature.

8.21  The following is an outline of the general principles applying to administration of snake antivenom. For detailed protocols, refer to the sources listed elsewhere in this chapter and to the Product Information leaflet provided with the antivenom:

a. resuscitate the patient as required (including intubation and mechanical ventilation, but avoiding tracheostomy);

b. correct first aid (pressure immobilisation and splint) should be applied if not already applied, and not removed if already in place;

c. an IV line should then be inserted;

d. **CSL SVDK** test (see Snake Venom Detection Kit Technical Information for details) should be performed, with specimen preferably taken from a bite site swab, or from urine or blood if necessary;
e. Blood should be collected on first presentation and at intervals for laboratory tests (coagulation studies, platelet count, and others such as urea, creatinine, potassium, enzymes, electrolytes, etc);

f. Resuscitative measures such as adrenaline should be on hand in case of an anaphylactic reaction. Respiratory support should also be available;

g. Urine should be collected and tested on first presentation and at intervals thereafter (test for haemoglobin and/or myoglobin);

h. A clinical decision is needed as to whether the patient requires antivenom (the Snakebite Management Chart of the CSL Antivenom Handbook will be of assistance). An adequate supply of antivenom will be needed. Snake antivenoms should only be administered if there is clear evidence of envenomation;

i. Selection of the type of antivenom to use will depend on the results of the CSL SVDK test. However, if the patient is severely envenomated, antivenom infusion should not be delayed whilst waiting for CSL SVDK results. Where a specific antivenom cannot be determined, polyvalent antivenom can be used;

j. The use of adrenaline pre-medication is controversial and should not be carried out without prior consultation with an experienced specialist;

k. Consult specialist help as required (see paragraph 8.6);

l. Administer antivenom. IV infusion is commenced with the patient lying down. Antivenom should be diluted with up to 1 in 10 times its own volume with an isotonic crystalloid solution such as saline, Hartmann's solution or dextrose, and given by IV infusion over the time frame recommended by the manufacturer's instructions. Administration should be slow at first but may need to be more rapid if the patient is critically ill;

m. First aid should be removed at a clinically appropriate stage, that is, only:

   (1) in the case of a severely envenomated patient, when antivenom administration has been instituted and the clinical situation has stabilised; or

   (2) in the case of a patient who has early symptoms suggestive of possible envenomation, or who has been bitten but appears symptom free, once an IV line has been inserted, CSL SVDK tests performed and other blood tests performed;

n. Continually check and record all vital signs;

o. Snake antivenoms should be given intravenously through a drip set. The contents of each vial should take about 15–30 minutes to run;

p. More antivenom may be required if the patient’s condition deteriorates or fails to improve; and
8.22 **Adverse events from snake antivenoms.** As snake antivenoms are prepared from horse sera, there is the potential for serious allergic reactions, including anaphylaxis. Adverse events may also be due to the concentrated protein solution opposing the effects of complement; this reactivity is reduced if antivenoms are diluted. Administration of antivenoms should only occur in a facility where full resuscitative facilities are available and tested. Adrenaline, antihistamine and steroids should be available for immediate parenteral administration in the event of an anaphylactic reaction. However, pre-treatment with adrenaline is controversial and is not recommended. If available, dilute adrenaline can be set up to be administered via an infusion pump through a side arm of the drip set.

8.23 The rate of allergic reactions to antivenom is reported to be between eight and 12.5 per cent, although less than one per cent will experience a major sensitivity reaction. Patients who have a history of allergies, or those who previously have come into contact with horse sera, are at higher risk. Possible adverse events may include:

- itching;
- urticaria;
- coughing;
- bronchospasm;
- increase in oral secretions;
- decrease in pulse volume;
- sudden decrease in blood pressure; and/or
- shivering or rigor attacks (if this occurs, it would usually occur within one hour of injection of the antivenom).

8.24 Some patients who have received antivenom may develop serum sickness from four to 14 days afterwards, the symptoms of which include rash, fever, joint pain and malaise. Serum sickness may be treated with oral steroids; prophylactic administration of oral prednisolone may be helpful.

8.25 **Action to be taken in the event of an adverse event to snake antivenom.** Action to be taken in the event of an adverse event to antivenom such as bronchospasm or a sudden drop in blood pressure is as follows:

- temporarily stop the infusion;
- administer adrenaline by:
  1. cautious IV infusion of diluted adrenaline (6 mg/100 ml, at approximately 10 mL per hour, via infusion pump, adjusting the rate as required by the response; or
(2) subcutaneous injection of 0.5 ml diluted (1:1000) adrenaline (in adults), repeating as required; or

(3) cautious administration of adrenaline intramuscularly if there is no response to a subcutaneous injection (there is a potential of major muscle haematoma with IM injection where there is venom-induced coagulopathy); or

(4) nebulised adrenaline (2 mL of 1:1000 solution) in cases where the main problem is bronchospasm;

c. recommence the antivenom infusion when the adverse event has been controlled;

d. corticosteroids and possibly antihistamines may also be needed to permit completion of the infusion.

8.26 Time factors in snake bite. A fatal outcome from snake bite may occur between three to 24 or more hours post bite. Many people bitten by venomous snakes do not develop any symptoms, or have only mild to moderate symptoms. In all cases, the application of correct first aid (pressure immobilisation bandage and splint) is essential as soon as possible after the bite or suspected bite; this will delay the onset of systemic circulation of venom. There should be adequate time to reach medical aid in most cases, even with potentially fatal bites. However, if the patient meets the criteria for administration of antivenom, it should be given as soon as possible after the bite.

8.27 Other factors in snake bite treatment. For further information on management of snake bite, see the CSL Antivenom Handbook (in particular the Snakebite Management Chart, and HLTHMAN volume 22). Important features of treatment include continuing to closely monitor the patient for significant signs or symptoms, and only administering antivenom if the patient develops significant signs/symptoms of envenomation and/or the blood tests shown abnormal results indicative of coagulopathy. After administration of antivenom where defibrination coagulopathy is present, it is necessary to wait for at least three hours after initial administration of antivenom before administration of further antivenom, to determine whether there is an apparent rise in fibrinogen. Blood tests should be repeated even if initial tests are normal, with blood tests being repeated every two to three hours. The patient should be admitted overnight and if the patient remains symptom free and the blood tests next morning are normal, he or she can be discharged.

8.28 Laboratory tests. The CSL Antivenom Handbook details the laboratory tests suggested for snakebite patients, including coagulation studies, platelet count, plasma/serum electrolytes, renal function (potassium, creatinine and urea) and creatine kinase.

8.29 In remote centres where coagulation studies cannot be performed, whole blood clotting time (WBCT) may be determined by placing 5–10 mL of venous blood from the patient in a glass test tube and measuring the time to clot. A clotting time in excess of 10 to 12 minutes would suggest coagulopathy. A WBCT in excess of 20 minutes without a clot is highly indicative of severe coagulopathy. At the same time as this test is run, a control should be run using blood from a staff volunteer, although
it is necessary to ensure that he/she is not taking anticoagulant drugs. If possible blood samples should also be taken and despatched urgently to a regional hospital laboratory, for coagulation studies, platelet count, plasma/serum electrolytes, renal function and creatine kinase.

8.30 Additionally, a ward test of urine (dipstix) may indicate myoglobinuria or haematuria.

Commonwealth Serum Laboratories Box Jellyfish Antivenom

8.31 The major Australian Box Jellyfish is Chironex fleckeri. Signs and symptoms of envenomation from Box Jellyfish are discussed in detail in the CSL Antivenom Handbook. Immediate first aid for a sting from this jellyfish comprises the topical application of vinegar to the stung area to inactivate the nematocysts. A person may collapse and suffer a cardiac arrest at the beach, but may survive with early CPR to achieve a return of spontaneous circulation (ROSC). It should be emphasised that no major effects occur with most people who are stung by this jellyfish. However, administration of Box Jellyfish Antivenom is required in life-threatening cases. Box Jellyfish Antivenom is produced by CSL and is derived from sheep IgG. Each vial of antivenom contains 20 000 units (comprising 1.5–4 mL) of neutralising capacity against Box Jellyfish venom.

8.32 Commonwealth Serum Laboratories Box Jellyfish Antivenom dosages and administration. Dosages and administration requirements are as follows. CSL Box Jellyfish Antivenom should be administered:

a. As soon as possible if there is evidence of life-threatening envenomation, including collapse, cardiac dysfunction or cardiac arrest, or respiratory complications. An initial dose of three vials (60 000 units) is recommended. It should be administered intravenously (IV), preferably diluted, through a drip set. It is strongly recommended that the Product Information leaflet provided with the antivenom be read before use, and if possible, that contact be made with a medical specialist in this field. Where a life-threatening condition persists, up to six vials (120 000 units) may be given consecutively Intravenously (IV).

b. In a non life-threatening situation, where there is severe pain which is not relieved by cold packs and parenteral narcotic analgesics. The dose is dependent on clinical judgment but it should be diluted, and administered IV.

c. Where there are cosmetic concerns for significant skin scarring (although the benefits of this are as yet unproven).

d. Consult specialist help as required (refer paragraph 8.6).

8.33 The administration of Box Jellyfish Antivenom should be used in conjunction with the topical application of vinegar to inactivate unfired nematocysts (stinging cells), cardiopulmonary resuscitation/respiratory support where necessary, and pain relief as required with cold packs and narcotic analgesics as indicated. Other measures may be required to control other symptoms due to life-threatening cardiotoxic effects of the venom. The efficacy of pressure-immobilisation bandaging as first aid for Box Jellyfish stings is currently the subject of much controversy.
Use of the antivenom by lay persons is normally precluded. However, if the injury occurs in an area remote from medical assistance and antivenom is available, intramuscular (IM) injection on the beach or in the ambulance by paramedical staff or specially trained personnel is justified in a life-threatening emergency, since death may otherwise occur within minutes of a serious Box Jellyfish sting. IM dosage is the contents of three vials, that is, a total of 60,000 units.

Adverse events to Commonwealth Serum Laboratories Box Jellyfish Antivenom. The only documented adverse event has been a mild generalised rash occurring about 20 minutes after Box Jellyfish Antivenom was administered. Although anaphylaxis following administration of Box Jellyfish Antivenom is a theoretical possibility, in practice, anaphylaxis has not been observed with this antivenom, but clinicians should set up before administering antivenom so that anaphylaxis can be treated if necessary. However, due to the rapidly acting and severe nature of Box Jellyfish venom, the need for rapid administration of antivenom may outweigh the need to be fully prepared to treat anaphylaxis. In the event of an adverse event to the antivenom (such as bronchospasm or a sudden drop in blood pressure) which is clearly attributable to the antivenom rather than the venom, the CSL Antivenom Handbook recommends temporary cessation of the antivenom infusion, subcutaneous injection of 1:1000 diluted adrenaline, 100 per cent oxygen and IV fluids. Nebulised adrenaline may assist where bronchospasm is the main problem. Once the adverse event is controlled, the antivenom infusion should be cautiously recommenced. Serum sickness may be treated with oral steroids.

Sea Snake bite

Bites usually occur on the extremities and the pressure-immobilisation first aid technique is effective. The principles of management of sea snakes are the same as those described for terrestrial snakes. Most sea snake bites do not result in significant envenomation. If envenomation has occurred, systemic signs usually occur within two hours of the bite. Symptoms of envenomation include:

a. rapid collapse and shock, which is a rare complication; or

b. generalised muscle aches, pains and stiffness of movement developing within one-half to one hour of the bite. Trismus (spasm of the jaw muscles) may also occur;

c. moderate or severe pain on passive movement on the arm, thigh, neck or trunk muscles developing within one to two hours of the bite; or

d. myoglobinuria (evident on inspection of the urine) three to six hours post-bite; or

e. elevation of plasma creatine kinase above 600 IU/L.

Sea Snake Antivenom is indicated only when there is significant envenomation, characterised by paralysis or myolysis. Sea Snake Antivenom is effective against severe envenomation even when administered up to two days after the bite.

Dosage and administration—Commonwealth Serum Laboratories Sea Snake Antivenom. All of the same precautions detailed in paragraphs 8.20 and 8.21
apply to the use of Sea Snake Antivenom. The initial dose is 1 to 3+ vials, depending upon the severity of the envenomation, although up to 10 vials have been used in severe cases. Do not use Tiger Snake Antivenom or Polyvalent Antivenom against Sea Snake envenomation.

**Stonefish and related species**

8.39 Stonefish are members of the family Scorpaenidae, scorpion or wasp fish. These differ in the number of spines and the lesser severity of the venom; however the venom from the Stonefish is very toxic. They are small fish, mostly less than 30 cm long, with a squat, grotesque appearance.

8.40 Signs and symptoms of envenomation from Stonefish and related species from the family are discussed in detail in the CSL Antivenom Handbook and in HLTHMAN volume 22. The symptoms of Stonefish envenomation include:

a. immediate, intense sharp pain. The pain radiates rapidly and extends far beyond the injury site and can last from several hours to several days;

b. muscle weakness and paralysis, and shock may occur;

c. local swelling, tenderness and blue discoloration of the sting site. The swelling may extend beyond the sting site;

d. generalised symptoms like nausea, vomiting, dizziness, collapse, cyanosis and respiratory distress may also occur, although they are uncommon; and

e. deaths have been reported in Indo-Pacific waters, with one being claimed to have occurred in Australian waters.

8.41 Commonwealth Serum Laboratories Stonefish Antivenom administration procedures. CSL Stonefish Antivenom is made from Horse IgG. It should only be given if envenomation has occurred. CSL Stonefish Antivenom is administered intramuscularly (IM). The amounts shown in Table 8-4 should be given. Consult specialist help as required.

<table>
<thead>
<tr>
<th>Number of spine puncture wounds</th>
<th>Number of vials of CSL Stonefish Antivenom</th>
<th>Units (at 2000 units per vial)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–2</td>
<td>1</td>
<td>2000</td>
</tr>
<tr>
<td>3–4</td>
<td>2</td>
<td>4000</td>
</tr>
<tr>
<td>More than 4</td>
<td>3</td>
<td>6000</td>
</tr>
</tbody>
</table>

8.42 Adverse events to Commonwealth Serum Laboratories Stonefish Antivenom. Adrenaline should be ready in advance to treat anaphylaxis should it occur. In the event of an adverse events to the antivenom (such as bronchospasm or a sudden drop in blood pressure), the CSL Antivenom Handbook recommends subcutaneous injection of 1:1000 diluted adrenaline, 100 per cent oxygen and IV fluids. Nebulised adrenaline may assist where bronchospasm is the main problem.
8.43 Serum sickness is a possibility with this antivenom, and oral steroid therapy may be required.

Red-back Spider

8.44 The Red-back Spider is present in many areas of Australia. This species is dark brown to black in colour, with a longitudinal red or orange stripe running centrally down the back. It has a globular shape, and is found in sheltered places such as logs or empty containers, where it is protected from the light. The web spun by the red-back is coarse and irregular. The female spider is potentially dangerous, with the male being much smaller, often not having any red markings and not regarded as being dangerous.

8.45 Signs and symptoms of envenomation from a Red-back Spider include:

a. a sharp stinging, or burning sensation when bitten;

b. localised pain, commencing some 10 to 40 minutes after the bite, which may spread throughout the body within from one to 24 hours, becoming quite severe; and

c. local sweating, usually profuse, accompanied by shivering, nausea, restlessness and muscular weakness, and mild to severe hypertension, may also occur.

8.46 Death does not normally occur after a Red-back Spider bite in a healthy adult.

8.47 CSL Red-back Spider Antivenom administration procedures. Each vial of Red-back Spider Antivenom, which is made from horse IgG, contains 500 units (comprising 1–1.5 mL) of neutralising capacity against the target venom. Diagnosis of a Red-back Spider bite is usually easily made because an individual who has been bitten will display a recognisable symptom pattern. Significant envenomation occurs in less than 20 per cent of bites. If more than 24 hours have elapsed since a patient was bitten, and they have few, if any, effects; withhold antivenom. If the patient is suffering significant effects of the bite, the sooner the antivenom is given the better.

8.48 CSL Red-back Spider Antivenom should be given as follows:

a. have appropriate equipment ready to treat allergic reactions, including adrenaline, antihistamine, and steroids, and have intravenous line ready;

b. administer one vial of CSL Red-back Spider Antivenom (500 units) IMI;

c. repeat the IMI dose in two hours if incomplete response or no improvement has occurred in the patient. In some cases a third vial may be necessary;

d. CSL Red-back Spider Antivenom may be effective when administered up to a week after the bite. However if more than 24 hours has elapsed since the bite, more than three vials may be required, but the time between doses should be extended, and IV administration, with appropriate precautions, could be considered; and
e. consult specialist help as required.

8.49 Alternatively, Red-back Spider Antivenom may be administered IV, diluted in 100 mL normal saline, over a period of 30 minutes. This is usually recommended after two ampoules have been administered IMI, or if the patient is severely envenomated.

8.50 Adverse events to Commonwealth Serum Laboratories Red-back Spider Antivenom. Adrenaline should be ready in advance to treat anaphylaxis should it occur. In the event of an adverse events to the antivenom (such as bronchospasm or a sudden drop in blood pressure), the CSL Antivenom Handbook recommends subcutaneous injection of 0.5 mL (=0.5 mg) 1:1000 diluted adrenaline for adults, 100 per cent oxygen and IV fluids. Nebulised adrenaline (2 mL of 1:1000 solution) may assist where bronchospasm is the main problem.

8.51 Serum sickness may occur from four to 14 days after administration of Red Back Spider Antivenom, but is reported to be quite rare. If it occurs, oral steroid therapy may be required. If the patient has a history of allergy, especially to equine protein, or has received equine protein before (eg has had Red-back Spider Antivenom before), the clinician may wish to consider giving a steroid intravenously prior to administration of the antivenom.

Funnel-web Spider

8.52 Funnel-web Spiders are particularly venomous, and any patient with a suspected Funnel-web Spider bite should be transported to hospital as soon as possible. First aid measures (pressure bandaging and immobilisation) should be applied and not released until antivenom administration commences. Signs and symptoms of envenomation from Funnel-web Spiders are discussed in detail in HLTHMAN volume 22. Many bites do not result in significant envenomation, but where envenomation is severe, the onset of dangerous symptoms can occur rapidly and death may occur within an hour in the absence of appropriate antivenom administration. Each vial of Funnel-web Spider Antivenom, which is made from rabbit IgG, contains 125 units of neutralising capacity against target venoms. The antivenom is freeze-dried and needs to be re-constituted with Water for Injection BP in accordance with the instructions on the label.

8.53 The following signs and symptoms may occur in patients who are suffering from significant envenomation from a Funnel-web Spider bite:

a. muscle fasciculation (either in the affected limb or remote from the bite site); this is first seen in the patient’s lips or tongue when the venom is spreading systemically;

b. increased salivation;

c. piloerection;

d. significant tachycardia, hypertension and dyspnoea, (hypotension may occur as a late sign); and

e. changes in the conscious state—confusion or a lower level of consciousness.
8.54 Commonwealth Serum Laboratories Funnel-web Spider Antivenom administration procedures. CSL Funnel-web Spider Antivenom is administered as follows:

a. have appropriate equipment ready to treat allergic reactions, but do not administer pre-treatment with adrenaline;

b. initial dose of antivenom is two vials, or up to four vials if envenomation is severe. Up to two further vials may be required;

c. repeat the dose in 15 minutes if there is no improvement; and

d. consult specialist help as required.

8.55 Serum sickness is a possibility with this antivenom, and oral steroid therapy may be required. However, delayed serum sickness is reported to be very rare with Funnel-web Spider Antivenom.

8.56 Adverse events to Commonwealth Serum Laboratories Funnel-web Spider Antivenom. In the event of an adverse reaction to the antivenom (such as bronchospasm or a sudden drop in blood pressure), the CSL Antivenom Handbook recommends subcutaneous injection of 1:1000 diluted adrenaline (0.5 ml/0.5 mg) initially for adults, 100 per cent oxygen and IV fluids. Adrenaline should be ready in advance to treat anaphylaxis should it occur. Nebulised adrenaline may assist where bronchospasm is the main problem. Antivenom infusion can be cautiously recommenced once the reaction has been controlled.

Commonwealth Serum Laboratories Paralysis Tick Antivenom

8.57 Signs and symptoms of envenomation from Australian Paralysis Ticks are discussed in detail in the CSL Antivenom Handbook and in HLTHMAN volume 22. An adult female tick which feeds for several days may cause the following symptoms:

a. ataxic gait,

b. general malaise, and

c. progressive paralysis leading to respiratory paralysis.

8.58 Commonwealth Serum Laboratories Paralysis Tick Antivenom administration procedures. CSL Paralysis Tick Antivenom is a freeze-dried preparation made from dog IgG, each vial containing 1000 units of neutralising capacity against Australian Paralysis Tick venom.

8.59 CSL Paralysis Tick Antivenom should be administered when there is significant systemic envenomation, characterised by progressive, major paralysis.

8.60 CSL Paralysis Tick Antivenom is administered as follows:

a. have appropriate equipment ready to treat allergic reactions, but do not administer adrenaline pre-treatment;

b. reconstitute each vial with 10 ml of Water for Injection BP;
c. dilute the reconstituted antivenom 1:10 with an isotonic crystalloid solution (eg. Hartmann’s solution or dextrose);

d. administer each vial IV through a drip set over a period of 15–30 minutes; and

e. consult specialist help as required.

8.61 Adverse reactions to Commonwealth Serum Laboratories Paralysis Tick Antivenom. Adrenaline should be ready in advance to treat anaphylaxis should it occur. In the event of an adverse event to the antivenom (such as bronchospasm or a sudden drop in blood pressure), the CSL Antivenom Handbook recommends cautious IV infusion of 6 mg/100 mL diluted adrenaline, 100 per cent oxygen and IV fluids. The initial infusion rate is about 10 ml/hour, being increased if there is no response within a few minutes, then decreasing when there is a response. Alternatively adrenaline can be administered subcutaneously (0.5 mL/0.5 mg initial dose for adults). Antivenom infusion can be cautiously recommenced once the reaction has been controlled. Nebulised adrenaline (2 ml of 1:1000 solution) may assist where bronchospasm is the main problem.

8.62 Serum sickness is a possibility with this antivenom, and oral steroid therapy may be required.

Storage and indenting of antivenoms

8.63 Antivenoms are indented through the Defence logistic system. Storage requirements are detailed in the Product Information for each item.
**ACRONYMS AND ABBREVIATIONS**

Unless stated otherwise, approved Australian Defence Force (ADF) acronyms and abbreviations are used within this publication. Externally sourced acronyms and abbreviations, herewith approved for ADF use, have the source designated in brackets following the definition, using the following legend:

**NATO**  *Allied Administrative Publication–6, NATO Glossary of Terms and Definitions, 2003 (AAP–6).*

**MIC**  *Multinational Interoperability Council Coalition Building Guide, 07 April 2003.*

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td>23vPPV</td>
<td>23-valent pneumococcal polysaccharide</td>
</tr>
<tr>
<td>ABL</td>
<td>Australian Bat Lyssavirus</td>
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<tr>
<td>ADF</td>
<td>Australian Defence Force</td>
</tr>
<tr>
<td>ADFP</td>
<td>Australian Defence Force Publication</td>
</tr>
<tr>
<td>ADHREC</td>
<td>Australian Defence Human Research Ethics Committee</td>
</tr>
<tr>
<td>ADT</td>
<td>adult diphtheria-tetanus vaccine</td>
</tr>
<tr>
<td>AEFI</td>
<td>adverse event following immunisation</td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquired immunodeficiency syndrome</td>
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<tr>
<td>AMA</td>
<td>Advanced Medical Assistant</td>
</tr>
<tr>
<td>anti-HB</td>
<td>antibody to Hepatitis B surface antigen</td>
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<td>Australian Prescription Products Guide</td>
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<td>Australian Red Cross Blood Transfusion Service</td>
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<td>Australian Disease and Environmental Alert Reporting System</td>
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<td>Australian Standard Vaccination Schedule</td>
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<td>Aviation Medical Officer</td>
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<td>Australian Venom Research Unit</td>
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<td>British Pharmacopoeia</td>
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<td>Centres for Diseases Control and Prevention (United States of America)</td>
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<td>Communicable Diseases Network Australia</td>
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<td>Director Military Medicine</td>
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<td>Hepatitis B immunoglobulin</td>
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<td>HMLP</td>
<td>Health Materiel, Logistics and Pharmacy</td>
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<td>Headquarters Joint Operations Command</td>
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<td>HRIG</td>
<td>human rabies immunoglobulin</td>
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<tr>
<td>HSP</td>
<td>health support plan</td>
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<td>International Certificate of Vaccination</td>
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<td>immunoglobulin</td>
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<td>immunoglobulin G</td>
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<td>investigational new drug</td>
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<td>key performance indicator</td>
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<td>Medical Employment Classification</td>
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<tr>
<td>MECRB</td>
<td>Medical Employment Classification Review Board</td>
</tr>
<tr>
<td>MenCCV</td>
<td>meningococcal C conjugate vaccine</td>
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<tr>
<td>MIMS</td>
<td>Monthly Index of Medical Specialties</td>
</tr>
<tr>
<td>MMR</td>
<td>measles, mumps and rubella</td>
</tr>
<tr>
<td>MO</td>
<td>Medical Officer</td>
</tr>
<tr>
<td>NHIG</td>
<td>normal human immunoglobulin</td>
</tr>
<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
</tr>
<tr>
<td>NO</td>
<td>Nursing Officer</td>
</tr>
<tr>
<td>NTM</td>
<td>notice to move</td>
</tr>
<tr>
<td>OAC</td>
<td>overseas administration cell</td>
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<tr>
<td>PHE</td>
<td>periodic health examination</td>
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<tr>
<td>PPD</td>
<td>purified protein derivative</td>
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<tr>
<td>ROSC</td>
<td>return of spontaneous circulation</td>
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<tr>
<td>SGADDF</td>
<td>Surgeon General Australian Defence Force</td>
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<tr>
<td>SMO</td>
<td>Senior Medical Officer</td>
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<tr>
<td>SOD</td>
<td>Strategic Operations Division</td>
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<tr>
<td>SSPE</td>
<td>subacute sclerosing panencephalitis</td>
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<tr>
<td>SVDK</td>
<td>snake venom detection kit</td>
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<tr>
<td>TB</td>
<td>tuberculosis</td>
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<tr>
<td>TCD</td>
<td>third country deployment</td>
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<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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<tr>
<td>TIG</td>
<td>tetanus immunoglobulin</td>
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<tr>
<td>TMUFF</td>
<td>temporary medically unfit for flying</td>
</tr>
<tr>
<td>TST</td>
<td>tuberculin skin test</td>
</tr>
<tr>
<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>UK</td>
<td>United Kingdom</td>
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<tr>
<td>UMR</td>
<td>unit medical record</td>
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<tr>
<td>USA</td>
<td>United States of America</td>
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<tr>
<td>VIG</td>
<td>vaccinia immunoglobulin</td>
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<td>VZV</td>
<td>varicella-zoster vaccine</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</tbody>
</table>
CHAPTER 1

CONDUCT OF HUMAN RESEARCH IN DEFENCE

This policy has been transferred from extant DI(G) ADMIN 24-3 dated 04 APR 2005. Only format and editorial amendments have been made. No substantive change has been made to the content or intent of this policy in the conversion.

INTRODUCTION

1.1 This policy addresses the requirements for obtaining clearance for conducting human research in Defence. It pertains to research conducted on humans where this research is supported in some way by Defence. It covers both authorisation to undertake the research and its ethical clearance. Human research in this context could include health, human performance, psychology, personnel and equipment trials research.

1.2 This policy is to be read in conjunction with the related readings.

AIM

1.3 The aim of this policy is to provide the framework to support the conduct of human research within Defence.

SCOPE AND APPLICABILITY OF THIS CHAPTER

1.4 This chapter is an administrative policy framework document (framework document) and applies to all Defence personnel.

1.5 The terms of a relevant contract may extend the application of this chapter to a contractor, consultant or outsourced service provider.

1.6 The Secretary and the Chief of the Defence Force require Defence personnel to comply with provisions in manuals unless the particular circumstances warrant departure from the provisions.

1.7 Some manual provisions support Defence personnel to comply with obligations that exist in legislation, other applicable laws or in Defence Instructions. Defence personnel must not depart from manual provisions in a way that would result in a breach of legislation, applicable laws or provisions in the Instruction.

1.8 When considering a possible departure from a manual the Secretary and the Chief of the Defence Force require Defence personnel to:

a. consider whether a proposed departure from the provisions is reasonable and justified in the circumstances and will produce a better outcome for Defence

b. consult their supervisor, wherever practicable, about a proposed departure – a properly informed decision may involve consulting the policy owner

c. be responsible and accountable for the consequences of departing from, or not adhering to, the content of a manual including where such departure or non-adherence results in a breach of applicable laws or leads to adverse outcomes for Defence.
1.9 Defence personnel may be subject to performance management, administrative action or in some circumstances, disciplinary action, where decisions or actions that depart from, or do not adhere to, manual provisions involve serious errors of judgement.

1.10 Failure to adhere to administrative policy may result in a breach of legislation or other legal requirement and sanctions under that legislation may apply.

1.11 Defence personnel who are authorised by the Secretary to execute contracts on behalf of the Commonwealth should consider whether there is a specific and documented reason to include in the terms of the contract the requirement for contractors, consultants and outsourced service providers to comply with the mandatory provisions of this manual and, if so, include such terms.

DEFINITIONS

1.12 **Research.** The National Health and Medical Research Council defines research as a systematic investigation to establish facts, principles or knowledge or a study of matter with the objective of obtaining or confirming knowledge.

1.13 **Human research.** In the context of human ethics, human research is that which is conducted using human volunteers or which accesses data collected from human volunteers. The National Health and Medical Research Council provides guidance on what constitutes human research in the ethical context. That document should be consulted particularly in cases of doubt as to the requirement for ethical review. In the context of human ethics, the document provides guidelines on what is human involvement and where there is the potential for the infringement of ethical principles. The body charged with the ethical review of human research in Defence is the Australian Defence Human Research Ethics Committee.

1.14 **Health research.** Health research is defined as that body of investigation aimed at increased understanding, maintenance or improvement of the physical and/or mental health of personnel. Further, it includes the examination of processes or other events that may directly or indirectly impact on the physical and/or mental health of personnel. The related readings provide further guidance.

1.15 **Human performance research.** Human performance research is defined as the group of investigations where the aim is to improve the normal performance, output and capability of humans to complete tasks and maintain or improve performance levels. This research has a focus on the development of human capacity and sustainability with respect to both physical and cognitive performance. Human performance research is further concerned with those aspects of human-systems integration that focus on the minimisation of the detrimental effects of systems and equipment on humans.


178 Australian Defence Human Research Ethics Committee
1.16 **Psychology research.** Psychology research covers the broad domain of the discipline of Psychology. In this context, it can be defined as the application of scientific methods developed within the discipline to the study of human behaviour. Within Defence it overlaps with, but extends beyond, health and human performance related research.

1.17 **Personnel research.** That personnel research which is within the human research context can be defined broadly as the utilisation of survey or focus group techniques to sample attitudes, beliefs or opinions of Defence members or their families. It represents a subset of Organisational Psychology and Human Resource research paradigms.

1.18 **Equipment trials.** Defence personnel are periodically required to participate in trials of new Defence equipment. In some circumstances the conduct of these trials may also cause them to fall within the human research framework.

**AUTHORISATION**

1.19 Before human research is conducted in Defence, it is to be assessed by a properly constituted responsible Defence organisation to ensure that Defence research priorities are met, Defence resources are properly applied and the research is to be carried out using sound scientific methodology. Groups and Services are responsible for implementing internal processes to ensure that research activities are appropriately prioritised, and that the applied methodology is scientifically sound.

**MENTAL HEALTH AND PSYCHOLOGY RESEARCH**

1.20 Within Defence, responsibility for the development and application of Defence psychology research policy rests with Mental Health and Research Evaluation within the Directorate of Strategic and Operational Mental Health.\(^{179}\)

**PERSONNEL RESEARCH**

1.21 The organisation primarily responsible for the conduct and coordination of personnel research within Defence is the Directorate of People Intelligence and Research\(^{180}\) within Defence People Group.

**EQUIPMENT TRIALS**

1.22 A number of Defence organisations conduct equipment trials. Organisations which conduct trials which might involve humans include, but are not limited to, the Directorate of Trials within the Defence Science and Technology Group and the Aircraft Research and Development Unit. The internal procedures of those organisations provide the mechanism for authorisation of such research.

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\(^{179}\) Directorate of Strategic and Operational Mental Health  
\(^{180}\) Directorate of People Intelligence and Research  
ETHICAL CLEARANCE

1.23 While not always the case, research involving humans in any of these areas may have the potential to infringe human ethics principles including privacy or safety issues. Where there is potential to infringe human ethics principles a protocol submission is to be made to Australian Defence Human Research Ethics Committee 181.

1.24 Consequent upon the Declaration of Helsinki and the World Health Organization Proposed Guidelines for Biomedical Research Involving Human Subjects, National Health and Medical Research Council 182 has recommended that: ‘In every institution in which human research is undertaken there must be a properly constituted institutional ethics committee.’

1.25 On the advice of the Surgeon General Australian Defence Force, the Chief of the Defence Force and the Secretary of Defence formed Australian Defence Human Research Ethics Committee (formerly the Australian Defence Medical Ethics Committee), a properly constituted human research ethics committee as laid down by the National Health and Medical Research Council. Australian Defence Human Research Ethics Committee reports to the Chief of the Defence Force and the Secretary annually on research during the previous year involving humans. The functions and structure of Australian Defence Human Research Ethics Committee are detailed in DHM Vol 3 Part 18 Chapter 1 183.

AUSTRALIAN DEFENCE HUMAN RESEARCH ETHICS COMMITTEE CLEARANCE

1.26 Australian Defence Human Research Ethics Committee reviews the ethics of, and where appropriate, approves proposals for human research to be conducted by, or on, Defence personnel and/or utilising Defence resources. Australian Defence Human Research Ethics Committee also monitors the progress of research protocols it has approved to ensure compliance with the conditions of that approval. No element of Defence is to perform or sponsor a human research project involving human volunteers, which requires human ethics consideration, without the clearance of Australian Defence Human Research Ethics Committee.

181 Australian Defence Human Research Ethics Committee


183 DHM Vol 3 Part 18 Chapter 1
1.27 Detail of when to seek Australian Defence Human Research Ethics Committee\textsuperscript{184} approval can be found on the National Health and Medical Research Council\textsuperscript{185} website. Further guidance is contained in the related readings. Key ethical principles to be applied are research merit and integrity; justice, beneficence; and respect. Key tests are the potential for doing harm to individuals, infringement of their privacy, the burden placed on them and their ability and freedom to give informed consent. Defence organisations are encouraged to develop criteria, as per the references, against which to assess research protocols in order to determine the requirement for human ethics clearance. If there is any uncertainty as to whether or not a proposal requires review by Australian Defence Human Research Ethics Committee, the research protocol is to be forwarded to Australian Defence Human Research Ethics Committee for consideration.

1.28 It is not possible to define all of the circumstances when human ethics review is required. The references indicated must be consulted; however the following guidance is provided without seeking to limit those circumstances. As examples, ethical clearance is required when:

\begin{itemize}
\item[a.] a research protocol involves invasive procedures
\item[b.] investigation explores the limits of the physiological or psychological integrity of humans
\item[c.] individual personal health information, including that obtained for other purposes, is to be used for human research. The use of de-identified information allows some health surveillance to be carried out without ethical clearance
\item[d.] there is an identified potential risk to the physical health or psychological wellbeing of humans participating in research protocols, including investigations and trials of man/machine systems, particularly where the protocol electively exposes individuals to this risk. Where other means could be used which would obviate the need for placing humans at risk, these should be used.
\end{itemize}

**PROTOCOL SUBMISSIONS**

1.29 The detailed procedures for formats, administrative requirements and methods of Health and Human Performance research protocol submissions are contained on the National Health and Medical Research Council website. For health and human performance research applications a single submission procedure addressing all the required aspects as per the National Health and Medical Research Council guidance is used. Protocols which do not involve health or human performance research, but which do require human research ethics consideration, may be submitted directly to Australian Defence Human Research Ethics Committee provided they have been assessed by the relevant responsible Defence organisation.

\textsuperscript{184} Australian Defence Human Research Ethics Committee

http://drnet.defence.gov.au/vcdf/Research/Pages/Policy\%20Documents.aspx#Australian\%20Defence\%20Human\%20Research\%20Ethics\%20Committee\%20(ADHREC)

1.30 Psychology, Personnel and Equipment trials research protocols are to be assessed in accordance with the requirements of the relevant authorities outlined in paragraphs 1.12. to 1.14. above before any submission to Australian Defence Human Research Ethics Committee 186.

1.31 Details of when submissions to Australian Defence Human Research Ethics Committee can be made are promulgated by the Australian Defence Human Research Ethics Committee secretariat. Strict time frames must be met and approvals obtained for submissions to be reviewed by Australian Defence Human Research Ethics Committee. Potential researchers must be cognisant of the requirements for prior assessment of submissions by bodies as determined by Service or Group procedure when timing submissions. Relevant web sites are:

a. For Australian Defence Human Research Ethics Committee 187

b. For Directorate of People Intelligence and Research 188

RELATED READINGS:

DHM Vol 3 Part 18 Chapter 1 – Human Research in Defence – Instructions for Researchers


National Health and Medical Research Council 2000 – Guidelines under section 95 of the Privacy Act 1988

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186 Australian Defence Human Research Ethics Committee

187 Australian Defence Human Research Ethics Committee

188 Directorate of People Intelligence and Research
National Health and Medical Research Council 2001– Guidelines approved under section 95A of the Privacy Act 1988

DEFENCE INSTRUCTIONS
(GENERAL)

Amendment
PERS 16–20
AMDT NO 1

Privacy of health information in Defence

Department of Defence
ANBERRA ACT 2600
30 July 2008

Issued with the authority of the Chief of the Defence Force and the Secretary of the Department of Defence pursuant to section 9A of the Defence Act 1903 for members of the Australian Defence Force.

Issued with the authority of the Secretary pursuant to section 20 of the Public Service Act 1999 for Department of Defence Australian Public Service employees.

NICK ARNE
Secretary

A.G. HOUSTON
Air Chief Marshal
Chief of the Defence Force

LIST B—ISSUE NO PERS B/11/2008

Single Service filing instructions

This instruction should be filed as:
1. VY PERS 31–52
2. ARMY PERS 124–30
3. AIR FORCE PERS 52–9

Sponsor:

Vice Chief of the Defence Force

Sponsor contact:

Director Health Capability Development

Review Date: 19 October 2008

Cancellation

DI(G) PERS 16–20 ISSUE NO PERS B/13/2005 of 19 OCT 2005 is to be amended as follows:

a. page amendments:

(1) remove existing pages 5–11 and replace with attached pages 5–12 (AL1).
Cancelled
PRIVACY OF HEALTH INFORMATION IN DEFENCE

References:
B. Defence Instruction (General) (DI(G)) PERS 36–2—Australian Defence Force policy on individual readiness (see http://defweb.cbr.defence.gov.au/home/documents/DATA/ADFPUBS/DIG/GP36_02.PDF)
D. DI(G) PERS 11–2—Notification of Service and Non-Australian Defence Force casualties (see http://defweb.cbr.defence.gov.au/home/documents/DATA/ADFPUBS/DIG/GP11_0.PDF)
E. Australian Defence Force Publication (ADFP) 06.1.4—Administrative inquisitors’ rules (see http://defweb.cbr.defence.gov.au/home/documents/adfdocs/ADFP/06_1_4.html)
K. DI(G) ADMIN 45–2—Reporting and Investigation of Aged Offences within the Australian Defence Organisation (see http://defweb.cbr.defence.gov.au/home/documents/DATA/ADFPUBS/DIG/GA45_02.PDF)

INTRODUCTION

1. The Privacy Act 1988 (Commonwealth) (the Act) governs the collection, management, use and disclosure of personal information, including health information, by government agencies, including their contracted health service providers, and some private sector organisations. Health information in Australia is protected by a combination of common law principles, such as the law of confidentiality, and professional and ethical codes of practice, as well as Commonwealth, State and Territory legislation. This Instruction provides direction for Defence health practitioners, Command, and other personnel on the management of health information in Defence. It is intended to be consistent with the Act. Where conflict is seen to exist between the matter to be brought to the attention of the sponsor and Defence Legal.

2. Privacy Principles that apply to the public and private sectors are contained in the Information Privacy Principles (IPPs) of the National Privacy Principles (NPPs) (reference A). Defence personnel have an obligation to be conversant with the IPPs and NPPs 7–10 when dealing with health information.

3. Legislative requirements for the handling of health information are laid down in reference A. Other Defence and administrative directives are listed in references B–L. Compliance is mandatory for Defence members and Australian Public Servant (APS) employees. Any perceived inconsistency between the references and this Instruction, or between the references and the Act should be brought to the attention of the sponsor of this Instruction and Defence Legal.
AIM

4. The aim of this Instruction is to outline the legislative and ethical requirements which are to be adhered to when managing health information within Defence.

DEFINITIONS

5. The following definitions apply in this Instruction:

a. **APS employee** means:
   (1) a person engaged under section 22 of the Public Service Act, or
   (2) a person who is engaged as an APS employee under section 72 of the Public Service Act.

b. **Authorised Investigation** means a matter that has been referred to the Head Defence Investigative Authority (HDIA) in accordance with DI(G) AD IN 45—entered into the Defence Policing and Security Management System, and then identified as requiring further inquiry.

c. **Authorised Investigator.** Defence investigators which includes named investigators that hold a Certificate IV in investigations and perform the duties of an investigator for the Director Fraud Investigation and Recovery, the Provost-Marshal or Defence Security Authority.

d. **Consent** means express consent or implied consent. All consent, whether express or implied, should be informed consent.

e. **Defence authority.** The Chief of Service or Vice Chief of the Defence Force, or their delegate, who is responsible for the carrying out of military operations.

f. **Defence Force** includes the Naval Reserve Cadets, the Australian Cadet Corps and the Air Training Corps.

g. **Defence member** means
   (1) a member of the Permanent Navy, the Regular Army or the Permanent Air Force; or
   (2) a member of the reserves who:
       (a) is rendering continuous full-time service; or
       (b) is on duty or in uniform.

h. **Defence health facility** means health facility recognised by Defence for the purposes of providing access to, administration, and delivery of health services on behalf of Defence, or authorised personnel acting on behalf of the facility.

Defence health practitioner means a health practitioner recognised by Defence for the purposes of providing health support on behalf of Defence. This definition includes, but is not limited to, Dental Officers (DO), Medical Administration Officers and medical administration staff, Medical Officers (MO), Nursing Officers (NO), Pharmacy staff, Psychology Officers, and enlisted personnel from the health trades including Medical Assistants and Psychology Examiners and Assistants. It also includes civilians acting on behalf of Defence, eg health professionals contracted to Defence (Contracted health practitioners and Sessionalist health practitioners (SHPs)) and Professional Service Providers (PSPs). Note that because contracted PSPs, Contract Health Practitioners and SHPs are not Australian Defence Force (ADF) members or APS employees, the relevant provisions of this Instruction are to be included in PSP Service contracts.
j. **DO.** Qualified dental practitioner, registered in an Australian State or Territory, who is a Defence member. It also includes a DO as recognised by any agreement which may be in place between the ADF and other parties.

k. **Defence personnel** are ADF members and Defence APS employees.

l. **Disclosure of health information.** Passing of health information by the record keeper to a party outside Defence, releasing it from effective Defence control. For the purposes of this Instruction, Defence is the record keeper of health information held in Defence health, psychology, personnel and other Defence records.

m. **Emergency contact** is an individual nominated by the member as the person to be advised in the event that the member becomes a casualty.

n. **Health information,** as defined in Section 6 of the *Privacy Act 1988,* means:

   (1) information or an opinion about:

      (a) the health or a disability (at any time) of an individual; or

      (b) an individual’s expressed wishes about future provision of health services to them; or

      (c) a health service provided, or to be provided, to an individual;

   (2) that is also personal information; or

   (3) other personal information collected to provide, or in providing, a health service; or

   (4) other personal information about an individual collected in connection with the donation, or intended donation, by an individual of their body parts, organs or body substances.

o. Health information collected by Defence inclusive of, but not limited to, immunisation records, pathology results, diagnostic imaging results, hospitalisation records, medical and dental examinations, psychological assessments, and specialist opinions.

p. **Health service** means:

   (1) activity performed in relation to an individual that is intended or claimed (expressly or otherwise) by the individual or person performing it:

      (a) to assess, record, maintain or improve the individual’s health; or

      (b) to diagnose the individual’s illness or disability; or

      (c) to treat the individual’s illness or disability or suspected illness or disability; or

   (2) the dispensing on prescription of a drug or medicinal preparation by a pharmacist.

q. **MO.** Qualified medical practitioner, registered in an Australian State or Territory, who is a Defence member. It also includes a MO as recognised by any agreement which may be in place between the ADF and other parties.

r. **NO.** Qualified nursing practitioner, registered in an Australian State or Territory, who is a Defence member. It also includes a NO as recognised by any agreement, which may be in place between the ADF and other parties.

s. **Operation (military).** A military action or the carrying out of a strategic, tactical, Service, training or administrative military mission.

t. **Operational.** Engaged in or on operations.
u. **Psychology Officer.** Qualified psychologist, usually registered in an Australian State or Territory, who is a Defence member or Defence APS employee. It also includes a psychologist as recognised by any agreement that may be in place between the ADF and other parties.

v. **Record** means:
   (1) a document;
   (2) a database (however kept); or
   (3) a photograph or other pictorial representation of a person.

w. but does **not** include:
   (1) a generally available publication;
   (2) anything kept in a library, art gallery or museum for the purposes of free, study or exhibition;
   (3) Commonwealth records as defined by subsection 3 (of the Archives Act 1983 that are in the open access period for the purposes of the Act;
   (4) documents placed by or on behalf of a person (other than an agency) in the memorial collection within the meaning of the Australia War Memorial Act 1980; or
   (5) letters or other articles in the course of transmission by post.

x. **Record keeper.** The Commonwealth as represented, for the purposes of Defence health information, by Defence

y. **Sensitive information,** as defined in Section 6 of the Privacy Act 1988, means:
   (1) information or an opinion about an individual’s:
      (a) racial or ethnic origin
      (b) political opinion, or
      (c) membership of a political association; or
      (d) religious beliefs or affiliations; or
      (e) philosophical beliefs; or
      (f) membership of a professional or trade association; or
      (g) membership of a trade union; or
      (h) sexual preferences or practices; or
      (i) criminal record;
   (2) that is also personal information; or
   (3) health information about an individual.

z. **Third party.** A party who is not involved in clinical management, diagnosis, treatment, administration or control of health information, or authorised to have access to the information by the record keeper, and who is other than the individual to whom the health information relates.

aa. **Use of health information** means the use of health information for the purposes described in this Instruction, with Defence maintaining control over the information.
Health information is classified as sensitive personal information and must be handled with due recognition of its sensitivity at all times, consistent with reference A and this Instruction. Personal health information in Defence is to be used or disclosed strictly on a ‘need to know’ basis.

POLICY

Purposes for which health information is collected in Defence

7. In Defence, health information is collected by a Defence health practitioner or health facility personnel in order to manage, diagnose, and treat an individual’s health on an ongoing basis, and to provide documentary evidence of the preparedness of an individual, from a health perspective, for operations (military) (reference B). Health information is also collected in Defence for the purposes of health research, subject to ethics approval of this research from the Australian Defence Human Research Ethics Committee (ADHREC), for operational health surveillance, and for clinical quality improvement activities, such as collection of data from Defence Health Facilities for Key Performance Indicators (KPIs) (see paragraph 21. below), public health reasons (reference C) and may be included in vocational assessments.

Consent

8. Consent for the use or disclosure of their personal health information can be given by Defence personnel at any time. The essential elements of consent are that it is based on sufficient information to make an informed choice, the person is competent (in ordinary sense) to consent, and that it is given freely and not obtained through coercion.

Consent for sharing of information between health practitioners

9. As set out in paragraph 7., health information is collected by Defence health practitioners (on behalf of Defence) in order to clinically manage and treat an individual’s health on an ongoing basis. It is an important component of the provision of optimal health services to individual members that all Defence health practitioners, who have a role in the care of the member, are able to access the entire health record of an individual member. In this regard, it is the responsibility of the primary treating health practitioner(s) to share a member’s personal health information with a member’s other treating practitioners, where such disclosure is necessary for the provision of coordinated health services or otherwise to the benefit of the individual member. This applies for example where a member suffers from a mental health disorder and is being managed by a Medical Officer, psychiatrist and/or psychologist. For optimal management, the treating practitioners will share and have access to all relevant Defence health information on the member’s condition.

Consent for disclosure of health information to a third party

10. When identifying health information is to be passed on to a third party or for the reasons described in paragraph 7., all reasonable steps should be taken by the health practitioner to obtain consent from the member for its release and to explain the reasons the information is required. In the event that the health practitioner believes release of health information is necessary despite a member not consenting to its release, the member must be advised that the information has been released, to whom it was released, the reasons it was released, and possible consequences of its release.

11. Notwithstanding paragraph 10. above, it is not necessary to seek further consent from the patient where:

a. the proposed use of health information is directly related to the purpose for which the information was collected; or

b. the member is reasonably likely to have been aware, or made aware at the time the health information was collected, that kind of disclosure is commonly made. Examples include where Defence publications outline such use or disclosure of information, or where such procedures are the usual Defence practice.
Use and release of health information—general principles

12. Personal information may be given to the member to whom it relates, unless there is strong evidence available to the health practitioner that to release the information will result in more harm to the member than withholding it from them.

13. The unique role of the ADF means that an individual's health information may be used for purposes other than for clinical management by Defence health practitioners. This use may include use by Commanding Officers (CO) or Defence units who administer the member, if it is necessary to enable the recipients of the information to monitor or manage the impact of the individual's health condition, and for the purposes of managing consequences which could arise if a member is not fit to fulfill operational requirements. Where information is released to manage operational consequences that may arise from a member's being unfit, the health practitioner is to record the fact that the information has been released. An example of this is where health information is released to a CO because the exception applies as described in paragraph 16. below. Defence personnel are to be informed when health information is collected that health information may be used in this way.

14. Any use for non-clinical purposes, or disclosure of health information to a third party, should be limited to that which is authorised or required to achieve the desired purpose for which the use or disclosure is made. Information released is not to include diagnosis unless there are exceptional circumstances where public health or public safety issues are pertinent. In these cases, consent from the individual to release the information should be sought. Where consent is not given, but exceptional circumstances as described in paragraph 16. apply, the information may be released by the appropriate authority. The release of the information and the circumstances in which it was released must be fully documented, and the individual should be informed that the information has been released. Advice should be sought from the senior medical officer or senior health officer of the health facility, or the most senior psychologist within the Psychology Section, if time permits.

15. Defence health personnel must keep appropriate authority informed of the health status of ADF members for the purposes described in paragraph 7. They are likely to provide sufficient information to fulfil these purposes. Where a health condition could have implications for operational purposes, information provided would normally include the location of member, expected time off work, likely changes to employability or deployability, and occupational restrictions, including rehabilitation management plan where applicable.

Release of health information—exceptional circumstances

16. Personal health information can be used or disclosed to others for purposes other than those described in paragraph 7. if:

   a. the Defence personnel concerned have consented to the use or disclosure; or

   b. the Defence health practitioner reasonably believes the use or disclosure is necessary to lessen or prevent a serious and imminent threat to an individual's life, health or safety, or a serious threat to public health or public safety, including in military workplaces and safety critical areas as per annex A; or

   c. the use or disclosure is required or authorised by law (eg statutory duties to notify certain infectious diseases or suspected child abuse (see paragraph 19.), or compliance with requirements of Courts of Inquiry and Boards of Inquiry (BOI) conducted as per reference E, Ombudsman, Freedom of Information (FOI) (reference F), subpoenas, warrants or court orders (see paragraph 37.–37); or

   d. where the Defence health practitioner has reason to suspect unlawful activities or reasonably believes it is necessary for certain law enforcement purposes; conditions to be met before use or disclosure are to be found in annex E; or

   e. the information concerns a patient who is incapable of giving consent, and is disclosed to a person legally responsible for the patient, such as next of kin (NOK) or the person holding power of attorney; for compassionate reasons or to enable appropriate care or treatment to be provided to the member; or

(Paragraphs 12–15 and 16 continued on next page.)
f. the use or disclosure is necessary for the compilation of statistics for public health or safety reasons, or for research that is approved by ADHREC, and is conducted in accordance with that Committee’s requirements; or

g. to an Investigating Officer appointed under reference E and pursuant to regulation 74A of the Defence Inquiry Regulations 1985; or

h. by the ADF and Commonwealth as authorised or required by law, in response to a formal complaint to which the health information may reasonably be considered relevant, whether the complaint is internal or external to Defence, and whether the complaint is against the ADF or particular Defence members provided that so far as practicable written consent is first obtained.

17. Defence personnel are to be informed of the possible uses to which health information may be put in Defence. For example, in the context of a military environment, health conditions which may adversely impact on an individual who has command responsibility for decisions which affect the lives or safety of military or other personnel, or personnel with responsibility for weapons or munitions may constitute exceptional circumstances with regard to use or disclosure of health information. Any such use or disclosure of health information should be limited to that which is required to achieve the desired purpose. Information so used or disclosed should not include diagnoses unless there are exceptional circumstances where public health or public safety issues are present, or where the safety of the individual, the unit, or others is at risk. In these circumstances, for example, where a member has undergone a significant change in emotional or mental stability, the health practitioner is to report that change in personal circumstance to the member’s appropriate Commander. The release of the information and the circumstances in which it was released must be fully documented.

18. Where a health practitioner is aware that a Defence member is holding a high level security clearance, and has undergone a significant change in emotional or mental stability, the health practitioner is to report that change in personal circumstance to the member’s Commander. The Commander may then exercise appropriate duty of care in relation to the information, including informing security channels as appropriate. Defence health practitioners should be pro-active in determining the member’s employment category and/or workplace responsibilities in order to minimise any potential risk to individual/public safety or national security.

19. Mandatory reporting. Defence and defence health practitioners have a legal requirement or authorisation to report some health conditions for public health or public safety reasons, or where an individual’s safety is at risk. Commonwealth legislation mandates the requirement for any MO to notify a licensing authority, for example, the Civil Aviation Safety Authority, of a health condition in a licence holder which has the potential to affect public health or public safety. Likewise, some infectious diseases require mandatory reporting as do suspected child abuse and, within Defence, the non-medical use of drugs. Compliance with written request from a Coroner, subpoena, court order or a Notice to produce may also result in the disclosure of health information (see paragraph 37–42).

20. Health referrals. For the purposes of health referrals, Defence health practitioners and Defence health facilities are only to disclose to external health providers specific information which the provider needs to carry out their function. This should be part of a detailed referral and may include test results, copies of previous related specialist reviews and previous specialist case notes. Where an entire Unit Medical Record, entire Form PM 341—Personal Dental Record—Folder, or Form AR 213—Psychological Documents Folder is to be sent to an external specialist or ancillary health practitioner, consent is to be obtained from the member. The entire Unit Medical Record/Unit Dental Record/Psych Folders should only be supplied at the request of the external health provider. The approval for release of information is to be documented as per annex B. Ex-serving members can authorise release of health information using Form PM 387—Authority to Release Health Information and/or Records for Ex-ADF Members.

21. KPIs. Reference Summary information, collected and used in genuinely unidentifiable form, such as KPIs, does not amount to personal information and as such is not a subject of reference A. Defence health facilities need to ensure, however, that the relevant information has been effectively de-identified and does not disclose information that identifies an individual. There is no requirement for normal operating audit data to be cleared by ADHREC. Where doubt exists, ADHREC may be consulted for guidance.
22. **Case conferences.** Case conferences involving non-health practitioners (e.g., social workers, chaplains) are held in some Defence health facilities with the express purpose of determining and implementing an approach to treatment of a member, which takes into account various holistic aspects of that member’s requirement. In Army, Personnel Review Boards and Boards of Studies are an important mechanism for Command to manage individuals. Health practitioners need to participate in this process and provide information necessary to allow effective management of personnel. Given the intricacies of the privacy requirements, Defence health facilities should obtain the consent of the Defence member to the collection, use and disclosure of health information about them by all the participants prior to the case conferences. Case conferences involving purely Defence health practitioners are using health information for its primary collection purpose, hence this use does not have implications for the IPPs.

**Security of health information**

23. The *Defence Security Manual* and Departmental Instructions are to be referred to for instruction on these matters.

24. **Physical security.** Filing cabinets, safes and compactus units containing records of personal health information are not to be left unlocked. A ‘clear desk policy’ is to be complied with to the maximum extent practicable, especially at the end of each working day. Records containing Defence health information are to be marked `XXX–IN–CONFIDENCE`, `MEDICAL–IN–CONFIDENCE`, `PSYCHOLOGY–IN–CONFIDENCE`.

25. **Information systems security.** Personal health information in Defence is to be used or disclosed strictly on a ‘need to know’ basis. Personnel with access to computer terminals where health information may be accessed or displayed are to be familiar with Defence Information and Policy Instructions on the use of electronic mail and internet services. See paragraph 27.–30.

26. **Reporting payments on the Australian Gazette Publishing System.** When entering payment details as per annex C and reference G, supervisors are to ensure that under no circumstances should a member’s name, unit treatment details including Medicare Benefit Schedule item numbers, be entered into the Gazette screen. Instead the operator should input generic details such as: ‘health consultation’, ‘health treatment’ or ‘psychological services’.

27. **Management of information held in Health Information Systems.** Defence electronic systems holding health information require appropriate access rights to guard patient privacy. In the case of health information held in HealthKYS, the Defence Health Service (DHS) Steering Committee has endorsed that access to Consultation Module, and therefore members’ health information, be restricted to Defence health practitioners as defined in this Instruction, on a ‘need to know’ basis. Authorised Defence health practitioners are to comply with the requirements of this Instruction in the handling of personal health information.

**Transmission of health information**

28. **Emailing and faxing of health information.** Record keepers of Defence health information have an obligation to ensure that personal information is securely stored. When storing and transmitting information electronically, security safeguards such as the Defence Intranet are necessary to ensure the information does not fall into the wrong hands or is misused. Care is to be taken to ensure information is sent to the correct email address or facsimile number. Identifiable personal health information is not to be sent over the internet unless it is encrypted.

29. Where an email is sent that does not have the name of an individual but does contain health information—a ‘hypothetical case’—and there is no way in which the identity of the person can reasonably be ascertained, the ‘hypothetical information’ is de-identified information and not ‘personal information’ for the purpose of the Act. However it is possible that if a very unusual health condition is described, a person may still be reasonably identified from that information. Care must be taken to ensure that the information cannot be linked to an individual.

30. **Mailing health information.** When health information is despatched to either external or internal health professionals it must be double enveloped. Instructions for the double enveloping procedure are to be found in annex D.
31. **Signals/messages.** If health information is transmitted by message or signal the drafter or releasing officer is to ensure that an appropriate security classification and privacy marking is used to protect that information.

**Reporting instructions for Notification of Casualty and for operational casualties**

32. Notification of Casualty (NOTICAS) for operational casualties reporting is particularly important in an operational setting. It provides the Commander Joint Operations Command, and Commanders with the greatest visibility of the status of the health and wellbeing of personnel deployed on operations, and allows Commanders to exercise their duty of care to the individual and the deployed force. Reference D outlines procedures for NOTICAS. Personnel responsible for verifying NOTICAS messages are to ensure that personal details, including member’s health condition, are protected through the use of appropriate privacy markings.

33. It is important that Defence is able to notify NOK or the emergency contact in the event of operational casualties. Deployed members are to be informed that this will occur during the pre-deployment briefing process. Information provided would normally include the member’s name, expected time off work, likely changes to employability or deployability, and occupational restrictions, including rehabilitation management plans where applicable.

34. Members may elect not to inform their emergency contact in cases of non-operational injuries. Notification then becomes a member’s responsibility, and the decision not to notify their emergency contact must be clearly documented in the member’s health documentation. If the member classified as Seriously Ill (SI) or Very Seriously Ill (VSI) states that they do not wish to have their emergency contact informed then the member is to be counselled about the consequences of failure to notify their emergency contact. If the member resolves that the emergency contact is not to be informed, then a statement to this effect must, where practicable, be included in their inpatient documentation. The statement should be signed by the member and witnessed by the admitting Defence health practitioner who is to ensure that the admitted member is positive they informed.

35. If a member is unconscious or unable to communicate the NOTICAS releasing authority is to use their discretion to decide whether the information should be passed to emergency contacts. If the Defence health practitioner makes an assessment that the member is medically incapable of making a rational decision about notification of their emergency contact, the health authority is to inform the CO to this effect. The CO will then be able to take this into account, along with other input from chaplains, psychologists, Defence Community Organisation, National Welfare Coordination Centre etc when making an informed decision as to whether to notify the emergency contact. If the decision is made to notify the emergency contact, this is to be documented in the inpatient documents and witnessed by another Defence Officer or Defence health practitioner.

36. Notification of non-defence personnel is restricted to workplace occurrences and are to follow procedures outlined in reference H.

**Release of health information for Courts of Inquiry, Boards of Inquiry and Investigating Officers**

1. These inquiries require documents to be produced, including personal health information. Health documentation is to be supplied to BOI and other Courts of Inquiry as per reference E.

2. Where practicable, the member should be asked to consent to the release of their personal health information for the purposes of Inquiries. If consent is not given, then the documents may be obtained as per the reference, and the member is to be informed if health documentation is released for this purpose.

**Release of health information for reporting a Notifiable Incident to a Defence Investigative Authority**

39. If a Defence health practitioner or counsellor receives a written request for health information about a member who is the subject of a Notifiable Incident report in relation to an alleged assault, sexual offence or a serious injury, subject to the consent of the member, or application of the consent exemption provisions of s.14 of the Act, patient confidentiality must be maintained in meeting the mandatory reporting requirements of the Defence Investigative Authority. For further guidance, references K and L refer, and advice may be sought from Defence Legal.
40. Where practicable, the member should be asked to consent to the release of their personal health information for the above purposes. If consent is not given, then the documents may be obtained as per the reference, and the member is to be informed if health documentation is released for this purpose, unless it can be reasonably shown that to do so would compromise the Investigation.

Release of health information to Service Military Police or Defence Investigators

41. Health information may be released to Service police agencies conducting an authorised investigation into an alleged offence. This falls within the exception as required or authorised by law. The disclosure of information is to be restricted to the specific information requested by the Authorised Investigator (AI) which they have determined as being necessary to the pursuit of the investigation. A note of the fact of the disclosure is to be made in the health record.

42. In Defence, the AI is to provide, in writing, a request for information relating to the authorised investigation. The request is to be limited to information relating to the specific area of interest or period of time which the authorised investigation relates to. Where health information is requested, considerations as per annex E are to be taken into account by the requesting AI. An example of a suitable request is in annex F. A copy of this request is to be retained in the member’s health records, together with documentation recording what information was supplied. Any dispute regarding the requested information is to be referred to the respective HDIA and Head Defence Health Services for arbitration. Disclosure in accordance with the terms specified in the relevant documents is also to occur on production of a warrant, subpoena or other such appropriately authorised demand.

43. Where doing so would not compromise the investigation, the member should be asked to consent to the release of their personal health information for the above purposes. If consent is not given, then the documents may be obtained as per reference E, the member is to be informed if health documentation is released for this purpose, unless it can be reasonably shown that to do so would compromise the Investigation.

Release of health information for Inquiries by the Commonwealth Ombudsman and the Defence Ombudsman

44. Where the Ombudsman requests personal information from Defence in the course of an investigation, Defence should request the Ombudsman’s Office that such request be put into writing, as a notice under s9(1) of the Ombudsman Act 1966. Any concerns regarding the information sought under the s9(1) notice should be brought to the attention of Defence Legal for advice.

Release of health information or Freedom of Information requests

45. If a Defence Health facility receives a written request for the release of a member’s Defence health record under the Freedom of Information Act 1982 (FOI Act), the relevant contact for the provision of these records is the Office of FOI, as outlined in reference F. The Defence Health facility is to refer the request to the Office of FOI for the earliest opportunity to facilitate a timely response, and is to inform the applicant of the referral. The relevant contact numbers are telephone (02) 6266 8855 or facsimile (02) 6266 8859.

A Psychology Section that receives a written request for access to or release of a member’s Psychology File or any part thereof outside of the FOI Act, should refer the request onto the Directorate of Psychology (DPSYCH) for their consideration and further action.

Release of health information for Coronial inquiries, subpoenas, Notices to produce

47. If a Defence Health facility receives a written request, subpoena or Notice to produce from a State or Territory Coroner (reference I) or court for a member’s Defence health record, the relevant contact for the provision of these records is the subpoena clerk in Directorate of Litigation in Defence Legal. The Defence Health facility should refer the request to Defence Legal at the earliest opportunity to facilitate a timely response to the request. The relevant contact numbers are telephone (02) 6266 8972, facsimile (02) 6266 8925. Defence Psychology Sections receiving such a request should forward that request onto DPSYCH for further action.

Medical Employment Classification Review Board

48. Health information related to Medical Employment Classification Review Board considerations may be released to personnel managers subject to the consent of the member as per reference J.
Release of health information to authorised representatives

49. DHS may release personal health information to an authorised representative acting on behalf of the person about whom the information is about. Written authorisation is the preferred record of consent and a copy should be placed on the individual’s health record. In exceptional circumstances, verbal consent may be given by the individual concerned and where this occurs, a Record of Conversation is to record the consent and a copy placed on the individual’s health record. Consent may also be given by personal (including legal) representatives, such as NOK and family members in respect of personnel under the age of 18 years.

CONCLUSION

50. Personal privacy issues in respect of health information are an important consideration in provision of health care in Defence. They should not, nor are they designed to paralyse the legitimate use of health information in Defence. Ethical issues must be taken into account and legislative requirements adhered to along with Defence’s requirements for operational concerns in the sensitive handling of health information in Defence.

Related publications


Annexes:
A. Safety critical areas
B. Consent for the release of health information—generic
C. Management of health privacy on the Australian Government Gazettaal System
D. Mail delivery of health records—double enveloping procedure
E. Factors to be taken into account regarding access to health information/records for the purposes of an investigation by Service police or Defence investigators
F. Example of request for access to health information/records for the purposes of an investigation by Service police or Defence Investigators

Sponsor: HDHS
SAFETY CRITICAL AREAS

1. Safety Critical Areas may be defined in single Service Instructions using the following list as guidance:

   a. all areas involved with the inspection, repair maintenance or certification of aircraft, ships, submarines, vehicles or equipment;
   b. all areas in which live firing is conducted;
   c. all areas involved with the inspection, repair maintenance or certification of safety equipment;
   d. all areas in which ordnance or weapons are stored;
   e. all area in which air traffic control functions are performed;
   f. all areas in which health services are delivered;
   g. all areas where refuelling operations are performed;
   h. all aircraft movement areas;
   i. all areas in which the loading or unloading of ships, aircraft, submarines or vehicles are being conducted;
   j. all areas in which gases, volatile liquids or chemicals are stored;
   k. operational areas and combat zones as defined in Australian Defence Force (ADF) operational orders and instructions;
   l. kitchens and galleys;
   m. within service vehicles;
   n. construction sites;
   o. in ships/boats/small craft/submarines as designated in Ship’s Standing Orders;
   p. aircraft in accordance with Service policy;
   q. all areas in which watermanship training, swimming or their training is occurring;
   r. all areas where physical training activities are conducted;
   s. all areas were diving operations are being conducted;
   t. ADF Command and Intelligence centres; and
   u. other areas and activities as designated by Functional Commands, Formation Headquarters and Commanding Officers/Officers Commanding provided these can be reasonably justified for reasons of safety.
Cancelled
CONSENT FOR THE RELEASE OF HEALTH INFORMATION—
GENERIC

EMPLOYEE ID

Rank

Given Names

Family Names

Unit

CONSENT FOR RELEASE OF HEALTH INFORMATION

Collection, storage and use or disclosure of personal information is subject to the Information Privacy Principles (‘IPPs’) as set out in section 14 of the Privacy Act 1988 referred to in this document as ‘the Act’.

Health information is to be managed in accordance with the Act and is given a privacy marking of STAFF-IN-CONFIDENCE or MEDICAL-IN-CONFIDENCE. The ‘need to know’ principle is to be strictly applied.

A Health Record for Defence personnel has been maintained of medical, dental and psychology services provided to them during ADF Service. Identifiable information or copies of health records may be given to other parties outside Defence, such as hospitals and private health practitioners, unless it is required by law or permitted under the Act.

REASON FOR RELEASE OF HEALTH INFORMATION

☐ Member of test

☐ Health practitioner

☐ Other (specify)

1 If a Defence member is unsure of the implications of releasing their health information, this may be discussed with the treating health practitioner.
CONSENT

I authorise release of my entire health record.

OR

I authorise release of information from my health records related to:

| Specific Injury or Health Condition |

OR

I do not authorise release of information from my health records.

NAME OF AUTHORISED PERSON OR AGENCY

Information is to be forwarded to the person or agency below:

| Name and Address of Authorised Agency (If applicable) |

| Member’s Signature | Name | Rank | Date |

Cancelled
MANAGEMENT OF HEALTH PRIVACY ON THE AUSTRALIAN GOVERNMENT GAZETTAL SYSTEM

THE REPORTING OF FEE-FOR-SERVICE OR CONTRACT PAYMENTS TO CIVILIAN HEALTH SPECIALISTS, WITH A TOTAL VALUE GREATER THAN $2000.00

1. Departmental Procurement Policy Instruction 6/2003—Notification of Gazettal Requirements outlines Defence requirements to report agency agreements, Commonwealth contracts and standing offers with an estimated liability (including Goods and Services Tax where applicable) of $2000 or more on the Gazette Publishing System (GaPS) (see http://www.contracts.gov.au/) within six weeks entering into the agreement. This refers to all purchases whether they are simple, complex or strategic.

2. Currently civilian practitioners provide specialist examinations and/or treatment to Australian Defence Force members for a fee-for-service payment. In these instances the service provider is regarded as a contractor and the Australian Defence Organisation has an obligation to list the contract on GaPS (through ROMAN). This includes individual consultations by the supplier for amounts less than $2000 that is subsequently combined on a single invoice that then exceeds $2000.

3. When entering payment details, all supervisors are to ensure that under no circumstances should a member's name, unit or treatment details, including Medical Benefits Schedule item numbers, be entered into the Gazettal screen. Instead the operator should input generic details such as: health consultation, health treatment or psychological services.

4. As detailed in reference G, however, to comply with Commonwealth gazettal requirements the details of the supplier (whether a natural person or business) and the amount of the contract must be provided on GaPS. The contractor must be notified by the liability delegate (at the time of contract signature or on the referral) should any single invoice exceed $2000 that their name, address and Australian Business Number will be placed on GaPS.

5. If the supplier is concerned about having their residential address gazetted, they should be requested to provide a post office box or alternative street address (such as the address of their solicitor or accountant), which can be used for gazettal purposes.

6. Purchasing officers should ensure that where a supplier nominates a post box address for gazettal purposes, they also be requested to also provide a street address for inclusion in the contract, in order to meet legal requirements for the serving of notices. This requirement is separate from those applying to gazettal.
Cancelled
MAIL DELIVERY OF HEALTH RECORDS—DOUBLE ENVELOPING PROCEDURE

1. For information classified RESTRICTED and XXX–IN–CONFIDENCE:
   a. a single sealed envelope is to be used;
   b. originator’s name, contact number and full address details on the front;
   c. at the discretion of the originator XXX–IN–CONFIDENCE information may be double enveloped and/or addressed to an addressee by name and/or appointment as follows:
      (1) inner envelope:
          (a) marked with the classification top and bottom, front and back;
          (b) originator’s name, contact number and full address details on the front;
          (c) address details addressee on the front and
          (d) flap gummed down.
      (2) outer envelope:
          (a) address details of the addressee on the front;
          (b) originator’s name, contact number and full address details on the front; and
          (c) flap gummed down.

Note
CABINET–IN–CONFIDENCE information is to be handled as CONFIDENTIAL.
FACTORS TO BE TAKEN INTO ACCOUNT REGARDING ACCESS TO HEALTH INFORMATION/RECORDS FOR THE PURPOSES OF AN INVESTIGATION BY SERVICE POLICE OR DEFENCE INVESTIGATORS

1. Consistent with the Act Information Privacy Principles and Health Bulletin 8/2004—Privacy of health information—interim advice, medical records of Defence members can be released in accordance with the exceptions outlined in these two documents, including where the disclosure may be necessary for the enforcement of criminal law, which for these purposes includes the Defence Force Discipline Act 1982.

2. Before using or disclosing the documents, the following conditions must be met:
   a. There must be at least a reasonable suspicion that an offence has occurred and that the medical records contain relevant material.
   b. The information contained in the medical record is ‘reasonably necessary’ in the enforcement of the criminal law.
   c. There should be no less intrusive, or more efficient or less expensive manner in which the relevant information can be obtained.
   d. The public interest in enforcement must be sufficiently strong to justify the intrusion.

3. In order to be certain that these requirements have been met, service police or the relevant medical section may well want to consult a legal office.

4. Any access to medical records obtained under this exception is limited to the purpose of ‘enforcement of the criminal law’. Service police will be restricted to examining only those parts of the medical record that are relevant to their investigation and they should identify what information is relevant when they request disclosure. In accordance with Principle 10(e) of the Act, the Defence Investigative Authority releasing the release of information will not use or disclose the information for a purpose other than the purpose for which the information is granted.

5. Service police should also make it clear to the medical record holder whether advising the member of the disclosure will compromise the investigation, in which case advice as to disclosure will have to be delayed until such time as no such compromise would occur. However, advice of disclosure must occur at some stage.
Cancelled
EXAMPLE OF REQUEST FOR ACCESS TO HEALTH INFORMATION/RECORDS FOR THE PURPOSES OF AN INVESTIGATION BY SERVICE POLICE OR DEFENCE INVESTIGATORS

STAFF–IN–CONFIDENCE (once filled in)

File Number
Correspondence Out Number

Action Addressee (xxxxxxxxxx)

REQUEST FOR THE RELEASE OF MEDICAL DOCUMENTS

1. The Defence Investigative Authority (Insert Relevant Agency) is current conducting an inquiry into a matter concerning (Insert Name and unique identifying details PMKey Number, Date of Birth etc).

2. To assist with this investigation, the Defence Investigative Authority (Insert Relevant Agency) requests that either the Medical File of (Insert name) be made available for examination or certified true copies of all documentation (from (insert start date) to (insert end date) be provided/relation to (insert matter or Medical condition of relevance) deleted). In examination of the Medical File, it may be necessary for Investigators to remove documentation, which may indicate the commission of a service offence. Any documentation removed will be replaced with certified true copies.

3. In accordance with the Information Privacy Principle 11(e), of the Privacy Act 1988, the disclosure of this information is reasonable for the protection of the public revenue (or insert other relevant authority under which a cess is being sought).

4. Further to this, in accordance with Principle 10(e) of the Act, the DIA receiving the released information will not use disclose the information for a purpose other than the purpose for which the information is granted.

5. Should you require further information the Primary Investigator, (insert relevant details) on (insert contact details) is the point of contact. Should you wish to discuss this matter further with the Head Defence Investigative Authority (Insert Relevant Authority) they may be contacted on (insert contact details).

NAME OF SENDE
RANK AND SERVICE
POSITION

TELEPHONE

Date

STAFF–IN–CONFIDENCE (once filled in)
CHAPTER 4

USE OF MEDICATIONS BY AIRCREW AND AIRCRAFT CONTROLLERS

This policy has been transferred from extant HD 311 dated 22 FEB 2011. Only format and editorial amendments have been made. No substantive change has been made to the content or intent of this policy in the conversion.

INTRODUCTION

4.1 Medical conditions have the potential to adversely impact the ability of aircrew and aircraft controllers to safely accomplish their duties. This is especially true of conditions which affect or have the potential to affect the individual’s judgement, consciousness, alertness, equilibrium, coordination, vision or speech. It is the responsibility of the Aviation Medical Officer (AVMO) to ensure that aircrew and aircraft controllers with any of these conditions are placed in Temporary Medical Unfitness for Controlling Duty (TMUCD) or Temporary Medical Unfitness For Flying (TMUFF) status until the condition has resolved.

4.2 Many medical conditions require treatment with medications to improve symptoms or resolve the condition. In cases where the condition is resolved or improved to the point that the symptoms or underlying pathology no longer pose a risk to aviation safety, the AVMO may wish to remove the individual from Temporary Medical Unfitness (TMU) status. However, the course of medication may extend beyond the time when symptoms resolve or may be required on a chronic basis. In these cases, it is vital that the AVMO consider the potential effects (both therapeutic and possible side effects) of the medications before returning the individual to full flying or controlling status. This policy is intended for use by qualified AVMOs in accordance with DHM Vol 2 Part 2 Chap 12—Aviation Medical Officer Support to the Australian Defence Force as well as other Medical Officers (MO) treating aircrew or other aviation related personnel in consultation with an AVMO in accordance with the following policies:

a. DHM Vol 2 Part 2 Chap 12
b. AAP 8000.010—Section 5, Chap 5, TMUFF
c. DHM Vol 2 Part 8 Chap 12—Immunisation

4.3 The following definitions apply for the purposes of this policy:

22 DHM Vol 2 Part 2 Chapter 12
24 DHM Vol 2 Part 8 Chapter 12
b. Aircrew:
   
   (1) **Army**—Pilot, Aircrewman Loadmaster, Aircrewman Technician, and Flight Test Engineer
   
   (2) **Navy**—Pilot, Maritime Aviation Warfare Officer, Aviation Warfare Instructor, Aircrewman, Fighter Controller, Flight Test Engineer, and Laser Airborne Depth Sounder (LADS) Flight Crew
   
   (3) **Air Force**—Pilot, Air Combat Officer, Flight Engineer, Flight Test Engineer, Loadmaster, Airborne Electronics Analyst, Crew Attendant, and Air Intercept Controller.

c. AVMO are permanent or Reserve Australian Defence Force (ADF) MO or civilian Contract Health Practitioners who have completed initial AVMO training and are current in training requirements as prescribed in **DHM Vol 2 Part 2 Chap 12**.

d. Ground Trial a period of time using a medication while not actively performing flying or aviation-related duties sufficient to exclude the potential for idiosyncratic or other types of reactions.

e. TMU is the general restriction from specialist duties.

f. TMUCD is the specific restriction from performing specialist duties as Joint Battlefield Airspace Controllers and ADF Uninhabited Aerial Vehicle Controllers.

g. TMUFF is the specific restriction from performing duty as active aircrew.

**POLICY**

**Prescription medication**

4.4 Medications may be divided into four different categories when considering their use in aircrew and aircraft controllers. These are:

a. Medications considered commonly understood and/or safe for use by aircrew and aircraft controllers on an occasional basis for minor symptomatic complaints or as prophylaxis during deployed operations. These may be taken without a TMU period assuming the underlying condition does not limit duty. Additionally, some medications require ground trial prior to operational use. Medications in this category may be used on a limited basis without consultation with an AVMO or Clinical Manager medical sailor. The AVMO assigned to the unit should ensure aircrew and aircraft controllers understand the appropriate use of these medications.

b. Medications generally considered compatible with aviation-related duties that may be prescribed by an AVMO after an appropriate ground trial to exclude the possibility of unacceptable adverse and idiosyncratic reactions has been completed. Continued use of the medication will typically require Unit Aviation Medical Employment Classification Review.

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25 DHM Vol 2 Part 2 Chapter 12

c. Medications with a less proven record of safety in aircrew and aircraft controllers or which are more prone to complications in the aviation environment may still be compatible with aviation related duty. However, their use will require an individualised ground trial and careful consideration in each individual typically requiring Central Aviation Medical Employment Classification Review (CAMECR) prior to approval for use during aviation related duties.

d. The final category of medications (including those NOT specifically listed) consists of those not compatible with flying or aviation related duties. In addition to action required by the underlying condition, use of these medications will require appropriate CAMECR action. CAMECR may infrequently result in the approval of these medications for aircrew and aircraft controllers but such should not be the expectation.

4.5 The list of Approved Medications for Aircrew and Aircraft Controllers includes many commonly prescribed medications, however, it is not meant to be comprehensive. The list shows if TMU is required, the length of required ground trial, and if CAMECR is required. This list is published on the Joint Health Command Medicine Formularies webpage and will be reviewed quarterly by the Commanding Officer Royal Australian Air Force Institute of Aviation Medicine (CO AVMED) with content updated as required. Input for changes may be submitted through CO AVMED who will circulate it through the Aviation Medicine Working Group for consideration and subsequent amendment as indicated.

4.6 Medications not found in the list may be used with aircrew and aircraft controllers as appropriate for their medical condition. However, the individuals must remain TMU until the underlying condition has resolved, the medication is no longer required and the effects of the drug have dissipated. This usually requires at least 24 hours from the last dose. Some exceptions to the 24-hour rule include:

a. immunisations (TMU 12 hours including Japanese Encephalitis Vaccine JESPECT; 72 hours in the case of Japanese Encephalitis Vaccine JE-Vax)

b. local or regional anaesthetics, dental or other minor procedure—minimum eight hours, which may be extended by MO or Dental Officer as applicable.

c. general, spinal, epidural anaesthesia or IV sedation (48 hours)

d. Ketamine (three weeks)

e. Mefloquine (four weeks)

f. Use of sleep inducing agents.

Sleep inducing agents

4.7 Sleep inducing agents may be considered operationally beneficial when operational requirements disrupt the normal sleep-rest cycles of ADF aircrew and aircraft controllers. The decision to use sleep inducing agents is a command responsibility and must be conducted in accordance with annex A. However, it is the responsibility of AVMOs to advise commanders and aviation related personnel of the risks of fatigue and the strategies that may be used to minimise such threats

26 Joint Health Command Medicine Formularies website https://objective/id:R10450235
including sleep inducing agents. If the commander decides that the use of such agents is justified, The AVMO will ensure this is implemented in accordance with specific guidance given in annex A.

**Medication for Malaria**

4.8 Operational deployment to malarious areas for periods longer than one-week will require aircrew and aircraft controllers to take antimalarial chemoprophylaxis and this requirement should be implemented in accordance with DHM Vol 2 Part 8 Chap 7—Malaria. Medications which may be used in aircrew and aircraft controllers include Doxycycline, Malarone, or Chloroquine, with each requiring a ground trial to exclude adverse effects. Mefloquine (trade name Lariam) is not authorised for aircrew and aircraft controllers. Inadvertent treatment with mefloquine requires a TMU period of four weeks after discontinuation of the medication.

**Over the counter preparations**

4.9 Vitamins and Herbal/Supplement preparations not addressed specifically should be used only with consultation between the member and the AVMO. Aircrew and aircraft controllers are to treat complementary medicines as they would any other over the counter medication. There is a potential for unforeseen consequences and aviation related personnel should consult an AVMO for advice prior to use. The potential effects (both therapeutic and possible side effects) of these preparations should be carefully considered and balanced against proven benefits before use. The AVMO assigned to the unit should be familiar with DHM Vol 2 Part 15 Chap 2—Use of dietary supplements and complementary medicines by Australian Defence Force personnel and ensure aviation related personnel understand the possible impact these preparations may have on flying or aviation related duties. Typical multivitamin preparations approved by the Australian Therapeutic Goods Administration may be taken at recommended doses without TMU.

4.10 Over the counter medications not addressed in the lists are nearly always used for conditions which are incompatible with aviation duty and should only be used when the individual is TMU with consultation with an AVMO.

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27 DHM Vol 2 Part 8 Chapter 07

28 DHM Vol 2 Part 15 Chapter 02
SUMMARY

4.11 This policy provides guidance for commanders, AVMOs, and other health professionals in the ADF to consider the use of prescription and over the counter medications in the treatment of aircrew and aircraft controllers and the potential impacts those medications may have on their ability to safely perform their aviation related duties.

Annex:

4A Use of sleep inducing agents in aircrew and Air Craft Controllers
ANNEX 4A
USE OF SLEEP INDUCING AGENTS IN AIRCREW AND AIR TRAFFIC CONTROLLERS

BACKGROUND

1. Military aviators are required to maintain optimum performance at all times. When such personnel become fatigued, as may result from sleep deprivation or disruption of normal sleep patterns, their alertness, and consequently their ability to sustain maximum performance is degraded. The effects of fatigue can only be fully ameliorated by quality sleep. Defence policy on Aircrew Fatigue Management is located in the Defence Aviation Safety Manual (DASM), Section 3, Chap 7, annex D

2. The ideal strategy to achieve optimal alertness in aircrew is to prevent fatigue and minimise unnecessary disruption of normal sleep patterns. This is best accomplished by ensuring that duty time is regulated appropriately within operational demands by providing for adequate amounts of quality sleep.

3. 

29 DASM, Section 3, Chap 7, annex D
30 Form PM 198

CHAPTER 1

PRIVACY OF HEALTH INFORMATION OF DEFENCE MEMBERS AND DEFENCE CANDIDATES

INTRODUCTION

1.1 *The Privacy Act 1988* governs the collection, management, use and disclosure of personal and sensitive information, including health information. Health information in Australia is also protected by a combination of common law principles, professional and ethical codes of practice, and Commonwealth, State and Territory legislation. This policy provides direction for the management of health information in Defence. It is consistent with the *Privacy Act 1988*. The Australian Privacy Principles, contained in Schedule 1 of the Act and *Australian Privacy Principle guidelines*, provides more detail.

1.2 Health information is collected, under principles of confidentiality, by and between health professionals and their patients. Defence personnel must manage health information in accordance with their confidentiality obligations, where applicable, and with the *Privacy Act 1988*.

POLICY STATEMENT

1.3 Health information is personal and sensitive information. Health information may only be collected, used, managed or disclosed in accordance with the *Privacy Act 1988*, confidentiality obligations and other relevant legislation. In Defence, health information is collected to assess, manage and treat an individual's health and also used to support the health component of Defence capability. Further details on the collection of health information within Defence is detailed in paragraph 1.23.

1.4 In accordance with *Privacy Act 1988*, defence health practitioners provide commanders and managers with information relating to the occupational and operational fitness of Defence members under their command or line of management. This is done for the purpose of meeting the commander or manager’s duty of care and Work, Health and Safety obligations. Refer to *MILPERSMAN*, Part 3, Chapter 2 – ‘Australian Defence Force Medical Employment Classification System’.

1.5 This policy sets out the policy on the collection, management, use and disclosure of personal health information of Defence members and Defence candidates.

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SCOPE AND APPLICABILITY OF THIS CHAPTER

1.6 This chapter is an administrative policy framework document (framework document) and applies to all Defence personnel.

1.7 The terms of a relevant contract may extend the application of this chapter to a contractor, consultant or outsourced service provider.

1.8 The Secretary and the Chief of the Defence Force require Defence personnel to comply with provisions in manuals unless the particular circumstances warrant departure from the provisions.

1.9 Some manual provisions support Defence personnel to comply with obligations that exist in legislation, other applicable laws or in Defence Instructions. Defence personnel must not depart from manual provisions in a way that would result in a breach of legislation, applicable laws or provisions in the Instruction.

1.10 When considering a possible departure from a manual the Secretary and the Chief of the Defence Force require Defence personnel to:
   a. consider whether a proposed departure from the provisions is reasonable and justified in the circumstances and will produce a better outcome for Defence
   b. consult their supervisor, wherever practicable, about a proposed departure – a properly informed decision may involve consulting the policy owner
   c. be responsible and accountable for the consequences of departing from, or not adhering to, the content of a manual including where such departure or non-adherence results in a breach of applicable laws or leads to adverse outcomes for Defence.

1.11 Defence personnel may be subject to performance management, administrative action or in some circumstances, disciplinary action, where decisions or actions that depart from, or do not adhere to, manual provisions involve serious errors of judgement.

1.12 Failure to adhere to administrative policy may result in a breach of legislation or other legal requirement and sanctions under that legislation may apply.

1.13 Defence personnel who are authorised by the Secretary to execute contracts on behalf of the Commonwealth should consider whether there is a specific and documented reason to include in the terms of the contract the requirement for contractors, consultants and outsourced service providers to comply with the mandatory provisions of this manual and, if so, include such terms.

DEFINITIONS

1.14 A list of definitions that apply to this policy is in annex A.
ROLES AND RESPONSIBILITIES

SURGEON GENERAL AUSTRALIAN DEFENCE FORCE

1.15 Surgeon General of the Australian Defence Force is responsible for establishing and maintaining procedures that are consistent with the Privacy Act 1988\textsuperscript{11} for use and disclosure of Defence members' health information by Defence health practitioner, and health administrative staff, where consent is not provided. Surgeon General of the Australian Defence Force is also responsible for the development of standards regarding the secure storage of Defence members’ health information at Defence health facilities and Joint Health Command.

CHIEF MEDICAL OFFICER DEFENCE FORCE RECRUITING

1.16 Chief Medical Officer Defence Force Recruiting is responsible for ensuring that the management of Defence candidates’ health information held by Defence Force Recruiting is managed in accordance with the Privacy Act 1988, related extant legislation and this policy. Chief Medical Officer Defence Force Recruiting is also responsible for the development of standards regarding the secure storage of Defence candidates’ health information at Defence Force Recruiting facilities.

DEFENCE HEALTH PRACTITIONERS

1.17 Defence health practitioners must:
   a. maintain professional confidentiality
   b. use and disclose health information in accordance with the Privacy Act 1988
   c. obtain and record consent (or the withdrawal of consent) for provision of relevant clinical information where appropriate
   d. document verbal consent contemporaneously in the health record of the Defence member or Defence candidate
   e. ensure external health service providers are provided with the Defence member’s relevant health information in order to facilitate the provision of comprehensive health care to the Defence member
   f. actively seek the informed and specific consent of the member when provision of health information to their Commander or supervisor would be of benefit in the management of their health condition, wherever possible
   g. provide advice to Commanders and managers. This will normally be limited to occupational or operational fitness information. Where consent has been provided by the Defence member or Defence candidate, additional clinical information may be provided to the Commander or manager in accordance with that consent
   h. provide relevant health information when consent has been refused or not given but release is permitted under the Privacy Act 1988.
HEALTH ADMINISTRATIVE STAFF

1.18 Health administrative staff must also maintain confidentiality and manage Defence members’ health information in accordance with the Privacy Act 1988. Administrative staff handling health records within Defence Force Recruiting facilities must also maintain confidentiality and manage Defence candidates’ health information in accordance with the Privacy Act 1988.

MANAGERS AND COMMANDERS

1.19 The manager or commander, on receipt of personal health information about a Defence member, must comply with the Privacy Act 1988, including limitations on the use or disclosure of that information, and must ensure that such information is secured appropriately.

DEFENCE MEMBERS

1.20 Defence members are responsible for participating in their health care; they are expected to be honest with their treating defence health practitioner to ensure that potential risk to themselves or others in the workplace is identified and managed, and to facilitate holistic and comprehensive health care. Defence members are encouraged to raise health concerns or issues which could affect their work performance with their Chain of Command to facilitate appropriate support in the workplace. Defence members are to be familiar with the Joint Health Command Privacy Statement – Health information of Defence members, which states the reasons for collection of personal health information and how health information will be used by defence health practitioners.

1.21 Defence members may provide their consent for the release of specific health information. They may also retract their consent to further release of their health information by notifying their treating authorised health professional.

DEFENCE PERSONNEL

1.22 All Defence personnel handling health information must comply with the Privacy Act 1988 and must secure such information appropriately.

MANAGEMENT OF HEALTH INFORMATION

1.23 Section 49 of the Defence Force Regulation 2016, requires Defence on behalf of the Commonwealth, to arrange for the provision of medical and dental treatment that is necessary to keep a Defence member fit for the performance of the member’s duties. Personal information, including health information is collected, used, managed and disclosed for this purpose.

COLLECTION OF HEALTH INFORMATION

1.24 In Defence, health information is collected:

a. by defence health practitioners in order to manage, diagnose, and treat an individual’s health on an ongoing basis, to advise commanders and managers of Defence members’ and Defence candidates’ suitability, from a health perspective, for military service, and to provide documentary evidence of the preparedness of an individual, from a health perspective, for military operations in accordance with MILPERSMAN\(^{15}\), Part 3, Chapter 1

b. to inform research conducted with appropriate ethics approval

c. for operational health surveillance

d. for clinical quality improvement activities and audits

e. for public health reasons

f. for inclusion in vocational assessments

g. to assist the management of claims in relation to repatriation, compensation, invalidity and other matters arising from military service, and to assist Defence in developing health standards for entry and ongoing military service.

USE OF HEALTH INFORMATION BETWEEN DEFENCE HEALTH PRACTITIONERS

1.25 The Defence member’s primary treating defence health practitioner may need to share that Defence member’s health information with their other treating health professionals, where such use is necessary for the provision of coordinated health services or otherwise to the benefit of the Defence member. For optimal management when appropriate, the treating health professionals will use and have access to all relevant Defence health information on the Defence member’s condition.

USE AND DISCLOSURE OF HEALTH INFORMATION –MANAGERS AND COMMANDERS

1.26 Defence members’ health information is subject to confidentiality provisions and generally will not be released to commanders and managers without consent. However, defence health practitioner will advise commanders and managers where necessary of any limitations on the ability of the Defence member to perform their duties. (See DHM Vol 2 Part 3 Chapter 1\(^{16}\) on Collection Use and Disclosure of Health Information by Defence Health Personnel).

\(^{15}\) MILPERSMAN


\(^{16}\) DHM Vol 2 Part 3 Chapter 1

1.27 Health information required to manage or reduce a serious threat to the life, health or safety of any individual may be released to those persons who are able to lessen or prevent that threat, for example, the Commanding Officer when a Defence member is at serious risk of self-harm in accordance with DHM Vol 1 Part 10 Chapter 1, and as permitted under the Privacy Act 1988. Health information may be disclosed to a responsible person, where the Defence member is incapable of giving consent in accordance with the DHM Vol 1 Part 1 Chapter 1.

DISCLOSURE OF HEALTH INFORMATION TO OTHER PERSONS ACTING ON BEHALF OF THE INDIVIDUAL

1.28 Defence health practitioner may release personal health information (where consent has been provided) to a responsible person acting on behalf of the person about whom the information is collected. Where the person is acting in accordance with a power of attorney or guardianship or other legal authority release of health information must be in accordance with DHM Vol 2 Part 3 Chapter 1 on Collection Use and Disclosure of Health Information by Defence Health Personnel.

DISCLOSURE OF HEALTH INFORMATION TO THE INDIVIDUAL CONCERNED

1.29 Health information may be given to the Defence member about whom it relates and should be managed by the authorised health professional. The Defence Privacy Policy provides information about how a Defence member can obtain personal information held by Defence.

USE OR DISCLOSURE OF HEALTH INFORMATION TO A THIRD PARTY

1.30 Health information may only be used by or disclosed to a third party (including non-health Defence personnel) without consent of the individual concerned in accordance with the Privacy Act 1988, such as where required by Australian law (eg subpoena, warrant or notice to produce). Further information is available in the Australian Privacy Principles in Schedule 1 to the Privacy Act 1988.

17 DHM Vol 1 Part 10 Chapter 1
19 DHM Vol 1 Part 1 Chapter 1
20 DHM Vol 2 Part 3 Chapter 1
NOTIFICATION OF AUSTRALIAN DEFENCE FORCE AND NON-AUSTRALIAN DEFENCE FORCE CASUALTIES

1.31 This policy does not negate the obligations of Defence personnel to report casualties in accordance with the Defence Casualty and Mortuary Affairs Manual Chapter 1. When a Defence member has a health condition necessitating notification, in accordance with the Defence Casualty and Mortuary Affairs Manual, essential health information will be used to inform specified Joint Health Command and single Service health representatives. When considered necessary, Joint Health Command or single Service health representatives may inform senior Defence managers (Service Chiefs or Directors General Personnel) of the member’s general health status. Specific clinical details are not to be provided to commanders or managers unless the Defence member has consented to release of health information. Disclosure of this information is necessary to ensure that Defence members are provided with optimal health, administrative and welfare support.

MONITORING AND REPORTING

1.32 The Defence Privacy Policy, provides advice on how a Defence member should submit a complaint if the Defence member is of the view that their privacy has been breached. Surgeon General of the Australian Defence Force is responsible for the monitoring of reported breaches of this policy by defence health practitioner and health administrative staff.

IMPLEMENTATION

1.33 DHM Vol 2 Part 3 Chapter 1 on Collection Use and Disclosure of Health Information by Defence Health Personnel provides guidance for defence health practitioner and health administrative staff on the use and disclosure of health information of a Defence member.

RELATED LEGISLATION AND POLICY

LEGISLATION


22 DCBSM
24 DHM Vol 2 Part 3 Chapter 1
Privacy Act [Australian Privacy Principles] (APPs), Schedule 1


State and Territory Health Practitioner Regulation National Law Acts: See the [Australian Health Practitioner Regulation Agency] website

State or Territory Coroner’s Acts

Public Health Legislation for the relevant jurisdiction

DEFENCE POLICIES

Australian Defence Force Publication (ADFP) 06.1.4 – Administrative Inquiries Manual

Records Management Policy Manual


Defence Casualty and Mortuary Affairs Manual, Chapter 3
http://intranet.defence.gov.au/home/documents/data/DEFPUBS/DEPTMAN/DCBSM/03.PDF

Military Personnel Policy Manual (MILPERSMAN),

DI(G) ADMIN 45–2 – The Reporting and Management of Notifiable Incidents

DI(G) PERS 15–5 - Management of the Use or Involvement with Prohibited Substances in the Australian Defence Force

DHM Vol 1 Part 13 Chapter 1 – Australian Defence Force Rehabilitation Program

DI(G) PERS 35–4 – Management and Reporting of Sexual Misconduct

DHM Vol 2 Part 3 Chapter 14 – Notifiable Condition Reporting in the Australian Defence Force

DHM Vol 2 Part 3 Chapter 1 – Collection, Use and Disclosure of Health Information by Defence
Joint Health Command Privacy Statement – Health Information of Defence members

DHM Vol 1 Part 1 Chapter 1 – Commander Joint health- surgeon General Australian Defence Force Authority and Responsibilities

DHM Vol 1 Part 10 Chapter 1 – Management of a Suicidal Episode in Defence

Defence Privacy Policy

Annex:
1A Definitions
ANNEX 1A

DEFINITIONS

Collects or collection occurs only if Defence collects the personal information for inclusion in a record or generally available publication.

Commander is a Defence officer, who by virtue of a delegation or instrument of appointment exercises authority and holds responsibility for assigned Defence personnel.

Consent means written (if practicable) or verbal timely, freely provided, and informed agreement or permission. Consent can be explicit or implied.

Defence candidate is a civilian who makes an application for entry to the Navy, Army or Air Force.

Defence means the Department of Defence and the Australian Defence Force.

Defence Australian Public Service employee is a person employed under the Public Service Act 199925 in the Department of Defence.

Defence civilian, as defined in the Defence Force Discipline Act 198226, means a person (other than a Defence member) who:

a. with the authority of an authorised officer, accompanies a part of the Defence Force that is:
   (1) outside Australia or
   (2) on operations against the enemy and
   (3) has consented, in writing, to subject him or herself to Defence Force discipline while so accompanying that part of the Defence Force.

Defence health practitioner. A Defence health practitioner means a person who:

b. is Defence personnel, a contractor or an outsourced service provider; and

c. provides a health service to a Defence member or candidate on behalf of Defence.

Defence locally engaged employee is any person engaged overseas by contract or under section 74 of the Public Service Act 1999.

Defence member, as defined in the Defence Force Discipline Act 1982 means

d. a member of the Permanent Navy, the Regular Army or the Permanent Air Force or

e. a member of the Reserves who is rendering continuous full time service, or is on duty or in uniform.

Defence personnel means all Australian Public Service employees in the Department of Defence, Defence locally engaged employees, Defence civilians, Defence members and the equivalents from other Defence organisations on exchange to Defence, and – where compliance is specified in the terms of contract – external service providers and outsourced service providers operating in Defence.

External service provider means a contractor, consultant and/or professional service provider engaged by Defence.

Manager means a Defence employee or Defence member who directs a range of human and physical resources and their associated financial responsibilities to achieve corporate objectives. A manager performs the role of a first-level supervisor where they have immediate subordinates, as well as the role of a second-level supervisor where they have Defence personnel supervised by those subordinates.

Outsourced service provider means an organisation or individual delivering specific services or supplies, usually against pre-defined milestones and deliverable requirements. The provider of the outsourced service is not subject to direct management by Defence.

Third party means a party who is not involved in clinical management, diagnosis, treatment, administration or control of health information, or authorised to have access to the information, and who is other than the individual to whom the health information relates.

Use of health information means the use of health information within Defence in accordance with the Privacy Act 1988, with Defence maintaining effective control over the information.

Definition as per the section 6FA of the Privacy Act 1988 Health information means:

f. information or an opinion about:
   (1) the health or a disability (at any time) of an individual or
   (2) an individual’s expressed wishes about the future provision of health services to him or her or
   (3) a health service provided, or to be provided, to an individual;
that is also personal information; or

g. other personal information collected to provide, or in providing, a health service or

h. other personal information about an individual collected in connection with the donation, or intended donation, by the individual of his or her body parts, organs or body substances or

i. genetic information about an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual.

**Health services** definition as per the section 6FB of the *Privacy Act 1988* means:

j. an activity performed in relation to an individual that is intended or claimed (expressly or otherwise) by the individual or the person performing it, either:
   
   (1) to assess, record, maintain or improve the individual’s health
   
   (2) where the individual’s health cannot be improved – to manage the individual’s health
   
   (3) to diagnose the individual’s illness or disability
   
   (4) to treat the individual’s illness, disability or injury or suspected illness, disability or injury
   
   (5) to record the individual’s health for the purposes of assessing, maintaining, improving or managing the individual’s health.

k. the dispensing on prescription of a drug or medicinal preparation by a pharmacist is a health service.

**Personal information** means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

l. whether the information or opinion is true or not

m. whether the information or opinion is recorded in a material form or not.

**Record** includes:

n. a document

o. an electronic or other device

but does not include:

p. a generally available publication

q. anything kept in a library, art gallery or museum for the purposes of reference, study or exhibition

r. Commonwealth records as defined by subsection 3(1) of the *Archives Act 1983*\(^{28}\) that are in the open access period for the purposes of that Act

s. records (as defined in the *Archives Act 1983*) in the care (as defined in that Act) of the National Archives of Australia in relation to which the Archives has entered into arrangements with a person other than a Commonwealth institution (as defined in that Act) providing for the extent to which the Archives or other persons are to have access to the records

\[t.\] documents placed by or on behalf of a person (other than an agency) in the memorial collection within the meaning of the *Australian War Memorial Act 1980*\(^{29}\)

u. letters or other articles in the course of transmission by post.

Note: For document, see section 2B of the *Acts Interpretation Act 1901*\(^{30}\)

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Responsible Person means:
v. a responsible person for an individual is:
   (1) a parent of the individual
   (2) a child or sibling of the individual if the child or sibling is at least 18
       years old
   (3) a spouse or de facto partner of the individual
   (4) a relative of the individual if the relative is:
       (a) at least 18 years old
       (b) a member of the individual's household
   (5) a guardian of the individual
   (6) a person exercising an enduring power of attorney granted by the
       individual that is exercisable in relation to decisions about the
       individual's health
   (7) a person who has an intimate personal relationship with the individual
   (8) a person nominated by the individual to be contacted in case of
       emergency.

w. in this section:
"child" : without limiting who is a child of an individual for the purposes of subsection
(1), each of the following is a child of an individual:
   (1) an adopted child, stepchild, exnuptial child or foster child of the
       individual
   (2) someone who is a child of the individual within the meaning of the
       Family Law Act 1975

"parent" : without limiting who is a parent of an individual for the purposes of
subsection (1), someone is a parent of an individual if the individual is his or her child
because of the definition of child in this subsection.

"relative" of an individual (the first "individual") means a grandparent, grandchild,
uncle, aunt, nephew or niece of the first individual and for this purpose, relationships
to the first individual may also be traced to or through another individual who is:
x. a de facto partner of the first individual or
y. the child of the first individual because of the definition of child in this
   subsection.

"sibling" of an individual includes:
z. a half-brother, half-sister, adoptive brother, adoptive sister, step-brother,
   step-sister, foster-brother and foster-sister of the individual

aa. another individual if a relationship referred to in paragraph (a) can be traced through a parent of either or both of the individuals.

"stepchild": without limiting who is a stepchild of an individual, someone is a stepchild of an individual if he or she would be the individual's stepchild except that the individual is not legally married to the individual's de facto partner.

Sensitive information means:

bb. information or an opinion about an individual's:
   (1) racial or ethnic origin
   (2) political opinions
   (3) membership of a political association
   (4) religious beliefs or affiliations
   (5) philosophical beliefs
   (6) membership of a professional or trade association
   (7) membership of a trade union
   (8) sexual orientation or practices
   (9) criminal record

that is also personal information; or

cc. health information about an individual

dd. genetic information about an individual that is not otherwise health information

ee. biometric information that is to be used for the purpose of automated biometric verification or biometric identification

ff. biometric templates
CHAPTER 1

PROVISION OF MEDICINES TO AUSTRALIAN DEFENCE FORCE MEMBERS

This policy has been transferred from extant HD 705 dated 11 APR 2011. Only format and editorial amendments have been made. No substantive change has been made to the content or intent of this policy in the conversion.

INTRODUCTION

1.1 DHM Vol 1 Part 4 Chap 1—Health care of Australian Defence Force personnel, provides policy on the health care entitlement of Australian Defence Force (ADF) members. Within the context of that policy there is a need to define the policy framework to determine entitlements to particular medicines.

AIM

1.2 The purpose of this chapter is to promulgate the policy that Joint Health Command (JHC) will use to determine the entitlement for particular medicines, and under what circumstances those medicines will be provided.

ENTITLEMENT

Policy

1.3 Medicines must only be provided by Defence as part of the wider provision of healthcare to ADF members to meet the requirements of DHM Vol 1 Part 4 Chap 1:

a. Defence will provide ADF members with medicines to support their healthcare requirements in order to meet the operational requirements of their Service.

b. The Surgeon General Australian Defence Force (SGADF) may, in some circumstances, constrain the entitlement to the provision of medicines by Defence, even when those medicines are available within the wider community, where provision of those medicines is not related to ADF service.

c. Medicines must not be provided by Defence when those medicines are part of, or in support of, healthcare which is not being provided by Defence.

d. Medicines, including over the counter medicines, must only be provided when clinically indicated.

e. Medicines can only be provided for the future use of members in support of approved preventive health programs or when specifically authorised to meet particular circumstances.

f. Medicines must only be provided by Defence for use by ADF members or other entitled personnel.

1 DHM Vol 1 Part 4 Chapter 1

1.4 Appropriately qualified Defence health practitioners (as defined in DHM Vol 1 Part 3 Chap. 1 – Privacy of health information in Defence) will decide whether a particular medicine or supplement will form part of Defence-provided health care to ADF members. This covers medicines prescribed or recommended by external consultants, or medicines requested by ADF members.

Medicines standards

1.5 **Policy.** Medicines provided to ADF members must be shown to be of appropriate quality, efficacious and cost-effective:

a. The quality of medicines in Australia is regulated by the Therapeutics Goods Administration (TGA). Defence will reference The Australian Register of Therapeutic Goods—Medicines (ARTG–M) to assess medicine quality.

b. The ARTG–M contains both TGA-registered (AUST–R) and TGA-listed medicines (AUST–L). Only AUST–R medicines have been assessed by TGA for efficacy.

c. Defence may reference sources such as the Pharmaceuticals Benefits Advisory Committee (PBAC) and Repatriation Pharmaceutical Reference Committee to determine cost effectiveness.

Application of Policy

Australian Defence Force Formulary

1.6 JHC will publish a list of routinely approved medicines for the provision of Garrison health support, called the ADF Formulary. Every attempt should be made to align prescribing and dispensing with the ADF Formulary. Some items in the ADF Formulary may be subjected to specific additional constraints. Defence electronic medicine management systems will be aligned to the ADF Formulary. The supply of medicines to Defence health facilities will be in accordance with the materiel and logistic management provisions of the Defence Procurement Policy Manual (DPPM).

1.7 Authority to provide medicines outside the ADF Formulary rests with the SGADF. SGADF may delegate that authority to Regional Health Directors or Service Operational Health Advisers (OHA).

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2 DHM Vol 1 Part 3 Chapter 1

3 The Australian Register of Therapeutic Goods – Australia https://www.ebs.tga.gov.au/

4 ADF Formulary https://objective/id:R10450235
Non-Defence Formulary references

1.8 Defence formularies do not provide for all possible medicine requirements to meet the requirements of DHM Vol 1 Part 4 Chap 1. The majority of requirements for ADF members will be met with medicines available through Defence formularies, supplemented when required by medicines available through public support mechanisms for the provision of medicines to the wider Australian community. These mechanisms include:

a. the Pharmaceutical Benefits Scheme (PBS) administered by Medicare Australia for the Department of Health and Ageing
b. the Repatriation Pharmaceutical Benefits Scheme administered by the Department of Veterans’ Affairs
c. State public hospital systems in accordance with their formulary arrangements.

1.9 Medicines to meet the operational health preparedness requirements of a member’s Service. Medicines which are not available through the methods stated in paragraph 1.6 to 1.8 may be supplied to an individual ADF member by Defence, but only in order to meet the operational health preparedness requirements of the member’s Service. An adequate evidence base supporting the use of the medicine is required and the proposed medicine must be cost-effective.

1.10 Clinical acceptability. Before a medicine which is not routinely available from Defence formularies is provided, all alternative routinely available Defence formulary medicines must be determined to be clinically unacceptable for that individual patient. This could include, but is not limited to, a documented inadequate therapeutic response, or greater adverse effects than would normally be anticipated, to the routinely available medicines.

1.11 Generic provision of medicines. Provision of medicines must be on a generic clinical-equivalence basis (DHM Vol 2 Part 15 Chap 8 —Management Procedures for Medical and Dental Materiel provides further guidance). Medicines must not be provided outside the generic policy framework where there is no evidence-based clinical reason for doing so.

1.12 External prescribers. External consultants used by Defence must be made aware, as appropriate, of the Defence constraints on the provision of medicines when ADF members are referred to them. This will include providing visibility of the ADF Formulary. Prescriptions written by external consultants that are compliant with Defence policy, including this Chapter, may be dispensed by Defence pharmacies. Prescriptions written by external consultants that are not compliant with Defence policy (after consultation with the consultant) must be referred to the treating Defence health practitioner (DHM Vol 2 Part 15 Chap 8 provides further guidance).

5 DHM Vol 1 Part 4 Chapter 1
6 DHM Vol 2 Part 15 Chapter 8
7 ADF Formulary https://objective/id:R10450235
Operational requirements

1.13 **Consolidated Index of Therapeutic Items (CITI).** JHC will publish a list of medicines available for routine issue to deployable and deployed health units as the CITI. The CITI is now contained within the ADF Formulary.

1.14 **Approving Authority.** Authority to provide medicines outside the CITI will be provided by DHLTH (J07) Headquarters Joint Operational Command (HQJOC). J07 HQJOC may delegate that authority to Joint Task Force Senior Health Officers.

1.15 **Unregistered medicines for ADF use.** Some medicines which are not TGA-registered are available for use in the ADF in order to meet operational imperatives, under a TGA exemption process. The Directorate of Health Materiel, Logistics and Pharmacy (HMLP) in JHC administers the approval process which includes oversight by the Australian Defence Human Research Ethics Committee (ADHREC). The procedures for obtaining and administering TGA exemptions for unregistered medicines are available from the Directorate of Military Medicine at JHC.DMM@defence.gov.au.

Medicines which are not an Entitlement for provision by Defence

1.16 Defence health services will normally discourage ADF members’ use of medicines which are not provided by Defence. Defence members must report to Defence health services the use of medicines or substances, in accordance with the following policies:

a. **DHM Vol 1 Part 4 Chap 1**—Health care of Australian Defence Force personnel.

b. **DHM Vol 2 Part 15 Chap 2**—Use of dietary supplements and complementary medicines by Australian Defence Force personnel.

c. **DHM Vol 2 Part 15 Chap 4**—Use of medications by aircrew and aircraft controllers.

1.17 It is in ADF members’ interests to have all medication use recorded in ADF electronic dispensing records to ensure their medication history is complete. Members can provide Defence pharmacies copies of prescriptions obtained privately for inclusion in the Member’s dispensing record. These items will be recorded in a manner that indicates the medicine was not provided by Defence as per the procedures contained in the PILS User Manuals.

1.18 When members decide to purchase medicines or supplements, that are not prescribed or issued as an entitlement, this will be at the members’ own expense without reimbursement.

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8 DHM Vol 1 Part 4 Chapter 1

9 DHM Vol 2 Part 15 Chapter 2

10 DHM Vol 2 Part 15 Chapter 4
1.19 Medicines which are a personal expense. Products which are presented as medicines, but which are a substitute for products which are normally a personal expense item for members should not normally be provided by Defence, even when they are a recognised and appropriate adjunct to the provision of healthcare.

Administration of Policy

1.20 Pharmacy and Therapeutics Committee. Interpretation and application of this policy, including oversight of the ADF Formulary and the CITI, will be undertaken by the Defence Pharmacy and Therapeutics Committee (PTC) in JHC.

1.21 National Support Area—regional administration for Garrison Health Support. Commanding Officers of Joint Health Units (JHU CO) are responsible for the implementation of this policy in the provision of Garrison Health Support. JHU CO must make use of the electronic facilities available at Central Dispensing Points (CDP) to monitor medicine usage. Local therapeutics committees should implement standard operating procedures to effect administration of the policies promulgated by this policy.

1.22 Administration in the Services and on deployed operations. Service OHA are responsible for the oversight of this policy within single Service units. DHLTH (J07) HQJOC is responsible for the oversight of this policy in units force-assigned to Joint Operations Command.

1.23 Responsibilities. All Defence health practitioners, particularly those prescribing and dispensing medicines, have a responsibility to ensure the implementation of this policy.

1.24 Provision of medicines as part of a trial. Medicines must not be provided to ADF members as part of a clinical trial without the prior approval of SGADF or delegate. The provisions of DHM Vol 3 Part 18 Chap 111—Human Research in Defence—Instructions for Researchers, including any requirement for clearance from the ADHREC must be complied with.

1.25 No-cost provision of medicines. Defence health practitioners and health facilities must not enter into supply arrangements for the provision of medicines to ADF members at no cost to Defence without the prior approval of SGADF or delegate, even though the medicines may have been granted TGA-registration. Typically such arrangements are made by suppliers pending PBAC consideration of potential PBS-listing.

1.26 Samples. Manufacturer samples of medicines, which are not otherwise routinely available to ADF members, must not to be provided to ADF members without the prior approval of SGADF. This includes samples of medicines which are provided to members by external consultants.

1.27 In order to comply with the intentions of Defence Instruction (General) Personnel 25–612—Conflict of Interest and Acceptance of Offers of Gifts and

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11 DHM Vol 3 Part 18 Chapter 1

12 Defence Instruction (General) Personnel 25-6
Hospitality, all samples of medicines provided to Defence health practitioners or to Defence health care facilities by manufacturers or their representatives, or provided to ADF members by external consultants, must be immediately surrendered to a CDP. Those samples can then only be provided to ADF members in accordance with a legitimate Defence prescription, consistent with this policy, as for any other medicine. This process forms part of the JHC compliance and assurance framework.

CONTACT

1.28 The point of contact within JHC is the secretariat of the PTC; attention Staff Officer 1 Pharmacy, DHMLP (email: JHCPHarmacy@defence.gov.au).
CHAPTER 1
SUPPLY, CONTROL, CARRIAGE, ISSUE AND ADMINISTRATION OF PHARMACEUTICALS

This policy has been transferred from extant DI(G) PERS 16-29 dated 05 JUN 2014. Only format and editorial amendments have been made. No substantive change has been made to the content or intent of this policy in the conversion.

PURPOSE
1.1 The Defence Act 1903 \(^{138}\) provides a regulation making power under section 124(1C) that medical and dental treatment includes the provision of services or goods (including pharmaceuticals) related to medical and dental treatment of a Defence member, or cadet, or a member of the family of a Defence member.

1.2 Department of Defence (Defence) is responsible for providing health care to Defence personnel, including the provision of pharmaceuticals to maintain fitness for duty. Defence must be capable of providing pharmaceuticals to Defence personnel both in garrison and remote medical contexts.

1.3 State and territory governments have a range of medicines and poisons legislation that imposes restrictions on who can supply these substances, to whom they can be supplied, how they can be supplied and in what circumstances. Compliance with this state and territory legislation has the potential to compromise or jeopardise the provision of pharmaceuticals in the health care of Defence members in operational, garrison and remote environments.

1.4 However, in accordance with Defence Regulation 2016 \(^{139}\), Groups and Services do not need to comply with state and territory laws if the supply of pharmaceuticals for the health care of Defence members complies with this policy.

POLICY STATEMENT
1.5 Defence provides pharmaceuticals required to maintain the fitness of Defence members. DHM Vol 2 Part 15 Chapter 8 \(^{140}\) – Health Materiel provides the policy and procedures governing the supply and control of pharmaceuticals within Defence. Services and Groups must comply with the provisions in this document.

SCOPE AND APPLICABILITY OF THIS CHAPTER
1.6 The aim of this policy is to authorise DHM Vol 2 Part 15 Chapter 8 as the policy and procedures manual governing the supply, control, carriage, issue and administration of pharmaceuticals within Defence.

1.7 This chapter is an administrative policy framework document (framework document) and applies to all Defence personnel.


\(^{140}\) DHM Vol 2 Part 15 Chapter 8

1.8 The terms of a relevant contract may extend the application of this chapter to a contractor, consultant or outsourced service provider.

1.9 The Secretary and the Chief of the Defence Force require Defence personnel to comply with provisions in manuals unless the particular circumstances warrant departure from the provisions.

1.10 Some manual provisions support Defence personnel to comply with obligations that exist in legislation, other applicable laws or in Defence Instructions. Defence personnel must not depart from manual provisions in a way that would result in a breach of legislation, applicable laws or provisions in the Instruction.

1.11 When considering a possible departure from a manual the Secretary and the Chief of the Defence Force require Defence personnel to:

a. consider whether a proposed departure from the provisions is reasonable and justified in the circumstances and will produce a better outcome for Defence

b. consult their supervisor, wherever practicable, about a proposed departure – a properly informed decision may involve consulting the policy owner

c. be responsible and accountable for the consequences of departing from, or not adhering to, the content of a manual including where such departure or non-adherence results in a breach of applicable laws or leads to adverse outcomes for Defence.

1.12 Defence personnel may be subject to performance management, administrative action or in some circumstances, disciplinary action, where decisions or actions that depart from, or do not adhere to, manual provisions involve serious errors of judgement.

1.13 Failure to adhere to administrative policy may result in a breach of legislation or other legal requirement and sanctions under that legislation may apply.

1.14 Defence personnel who are authorised by the Secretary to execute contracts on behalf of the Commonwealth should consider whether there is a specific and documented reason to include in the terms of the contract the requirement for contractors, consultants and outsourced service providers to comply with the mandatory provisions of this manual and, if so, include such terms.

**DEFINITIONS**

1.15 A list of definitions that apply to this policy is in annex A.

**ROLES AND RESPONSIBILITIES**

1.16 Commander Joint Health, as Surgeon General Australian Defence Force, is responsible for the clinical control of therapeutic goods including pharmaceuticals in Defence. Commander Joint Health is also responsible for reviewing this policy and maintaining all related health policy. **DHM Vol 2 Part 15 Chapter 8** describes the

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141 DHM Vol 2 Part 15 Chapter 8

responsibilities of Groups and Services for the supply and control of therapeutic goods including pharmaceuticals.

**SUPPLY AND CONTROL OF PHARMACEUTICALS THAT ARE SCHEDULED MEDICINES**

1.17 Commonwealth, state and territory legislation, regulations and legislative instruments provide a framework that controls the supply, carriage, issue and administration of therapeutic goods that are either used in Australia or exported from Australia. However, [Defence Regulation 2016][142] states that the provision of medical or dental treatment that is necessary to keep a Defence member fit for the performance of the Defence member’s duties is not required to be in accordance with a law of a State or Territory if the provision of the treatment complies with a Defence Instruction (General). Further, the supply of pharmaceuticals necessary to keep a Defence member fit for the performance of the Defence member’s duties is not required to be in accordance with a law of a State or Territory if the supply complies with a Defence Instruction (General).

**AUTHORITY TO SUPPLY, CONTROL, CARRY, ISSUE OR ADMINISTER PHARMACEUTICALS**

1.18 Defence recognises that Defence personnel may need to carry, issue or administer pharmaceuticals within their scope of practice while unsupervised in operational, garrison and remote contexts. [DHM Vol 2 Part 15 Chapter 8][143] provides the following:

a. authority for specified Defence personnel to be supplied with, to carry, to issue or to administer pharmaceuticals within their scope of practice

b. procedures for the approval of Defence personnel who are not Authorised officers

c. procedures for the supply of pharmaceuticals to Defence personnel who are not Authorised officers

d. procedures for the control of pharmaceuticals

e. procedures for the carriage, issue and administration of pharmaceuticals by Defence personnel who are not Authorised officers.

1.19 Groups and Services must comply with the requirements of [DHM Vol 2 Part 15 Chapter 8][143] when approving Defence personnel who are not Authorised officers to carry, issue and administer pharmaceuticals. When approved, these Defence personnel must comply with the requirements of [DHM Vol 2 Part 15 Chapter 8][143] when carrying, issuing and administering pharmaceuticals. These requirements include, but are not limited to:

a. circumstances when approval can be given

b. approval delegations, limitations and documentation

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[143] DHM Vol 2 Part 15 Chapter 8

C. assessment of currency and competencies of persons to be approved.

**COMPLIANCE**

1.20 This policy is issued under section 9A of the *Defence Act 1903*\(^{144}\) by the Chief Operating Officer and the Vice Chief of the Defence Force in accordance with powers delegated to them, to exercise jointly, by the Secretary of the Department of Defence and the Chief of the Defence Force under subsection 120A(3B) of the *Defence Act 1903*.

1.21 Defence personnel who award or manage contracts must include the requirement:

a. that external service providers must comply with the mandatory requirements of this Instruction in the terms of the contract, where this policy is directly relevant to the work the external service provider is performing for Defence

b. outsourced service providers must comply with the mandatory requirements of this policy in the terms of the contract only when there is a specific and documented reason for doing so.

c. Where it is a term of the contract, failure by an external service provider or an outsourced service provider to comply with the mandatory requirements of this policy, may result in a breach of contract.

1.22 All Defence personnel and external service providers, where compliance is a term of their engagement, must comply with the mandatory requirements of this policy. Outsourced service providers are not required to comply with the requirements of this policy unless there is a specific and documented reason for doing so and compliance has been included as a term of their contract.

1.23 A mandatory requirement of this policy is identified through the use of the word must.

1.24 The mandatory requirements of this policy constitute a general order to Defence members for the purposes of the *Defence Force Discipline Act 1982*\(^{145}\). Non-compliance with any mandatory requirement may result in disciplinary action being taken in accordance with the *Defence Force Discipline Act 1982*.

1.25 The mandatory requirements of this policy are intended to have effect also as a direction to Defence employees by the Chief Operating Officer for the purpose of subsection 13(5) of the *Public Service Act 1999*\(^{146}\) (subsection 13(5) forms part of the Australian Public Service Code of Conduct). Accordingly, non-compliance by Defence employees with any mandatory requirement may be referred for investigation and possible sanction in accordance with the *Public Service Act 1999*.

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MONITORING AND REPORTING

1.26 Commander Joint Health is the owner of health materiel policy in Defence. Commander Joint Health is also responsible for governance of therapeutic goods. Groups and Services are responsible, on behalf of the policy owner, for monitoring compliance with the governance requirements for health materiel. DHM Vol 2 Part 15 Chapter 8\(^\text{147}\) contains health material governance requirements.

IMPLEMENTATION

1.27 This policy authorises DHM Vol 2 Part 15 Chapter 8 as the primary policy governing the supply, control, carriage, issue and administration of pharmaceuticals within Defence.

1.28 All Groups and Services responsible for the delivery of health materiel or health care must:

a. promulgate all processes and procedures required for the effective implementation of DHM Vol 2 Part 15 Chapter 8 within six months of this policy being issued

b. include compliance with this policy in contractual documentation.

RELATED DOCUMENTS

1.29 Annex B contains a list of documents that are related to this policy.

Annexes:
1A Definitions
1B Related documents

\(^{147}\) DHM Vol 2 Part 15 Chapter 8

ANNEX 1A
DEFINITIONS

**Authorised officer.** An authorised officer is any military officer or civilian (employed or contracted by the Department of Defence) who is registered as a medical practitioner, dental practitioner, nurse practitioner, pharmacist or veterinarian and who is employed in that capacity and is working within their scope of practice.

**Defence.** Defence means the Department of Defence, Australian Defence Force and the Defence Materiel Organisation.

**Defence Australian Public Service employee.** A Defence Australian Public Service employee is a person employed under the [Public Service Act 1999](https://www.comlaw.gov.au/Series/C2004A00538) in the Department of Defence.

**Defence Civilian.** A Defence civilian, as defined in section 3 of the [Defence Force Discipline Act 1982](https://www.comlaw.gov.au/Series/C2004A02711), means a person (other than a Defence member) who:

a. with the authority of an authorised officer as defined in the [Defence Force Discipline Act 1982](https://www.comlaw.gov.au/Series/C2004A02711), accompanies a part of the Australian Defence Force that is outside Australia, or on operations against the enemy, and

b. has consented, in writing, to subject themselves to Australian Defence Force discipline while so accompanying that part of the Australian Defence Force.

**Defence Member.** A Defence member, as defined in section 3 of the [Defence Force Discipline Act 1982](https://www.comlaw.gov.au/Series/C2004A02711), means:

a. a member of the Permanent Navy, the Regular Army or the Permanent Air Force; or

b. a member of the Reserves who: is rendering continuous full-time service; or is on duty or in uniform.

**Defence Personnel.** Defence personnel means all Defence employees, Defence locally engaged employees overseas, Defence civilians, Defence personnel and the equivalents from other Defence organisations on exchange to Defence.

**External service provider** means a contractor, consultant and/or professional service provider engaged by Defence.

**Medicine.** Medicines as defined by the Therapeutic Goods Administration are:

a. therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal.

b. any other therapeutic goods declared by the Secretary to the Department of Health, for the purposes of the definition of therapeutic device, not to be therapeutic devices.

**Pharmaceutical item.** Pharmaceutical items, as defined by the Organisation for Economic Cooperation and Development (as described in its System of Health Accounts,) are prescription medicines, over-the-counter medicines and other medical

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non-durables dispensed to out-patients. These include medicinal preparations, branded and generic medicines, drugs, patent medicines, serums and vaccines, vitamins and minerals, and oral contraceptives and a wide range of medical non-durable goods, which are either single use items (such as band-aids and condoms), or have limited re-usage (such as bandages). With respect to regulation 58E—‘Pharmaceuticals’ of the Defence Regulations 2016 150 includes any ingredient, compound, material or preparation that is mentioned in the current Poisons Standard prepared under subsection 52D (2) of the Therapeutic Goods Act 1989 151.

Supply. With respect to section 49 —of the Defence Regulations 2016 in relation to pharmaceuticals, includes any activity in relation to pharmaceuticals, such as transport, storage, and possession, that is necessary in order to comply with this regulation.

Therapeutic goods. The Therapeutic Goods Administration defines therapeutic goods as products for use in humans in connection with:

a. preventing, diagnosing, curing or alleviating a disease, ailment defect or injury
b. influencing, inhibiting or modifying a physiological process
c. testing the susceptibility of persons to a disease or ailment
d. influencing, controlling or preventing conception
e. testing for pregnancy.

ANNEX 1B

RELATED DOCUMENTS

AUSTRALIAN DEFENCE FORCE PUBLICATIONS

DHM Vol 2 Part 15 Chapter 8 —‘Health Materiel’

LEGISLATION

Controlled Substances Act 1984 (South Australia)

Controlled Substances (Poisons) Regulations 2011 (South Australia)


Drugs, Poisons and Controlled Substances Act 1981 (Victoria)

Drugs, Poisons and Controlled Substances Regulations 2006 (Victoria)

Health Act 1937 (Queensland)

Health (Drugs and Poisons) Regulation 1996 (Queensland)

Health Regulation 1996 (Queensland)

Medicines, Poisons and Therapeutic Goods Act 2008 (Australian Capital Territory)

Medicines, Poisons and Therapeutic Goods Regulation 2008 (Australian Capital Territory)

Poisons Act 1971 (Tasmania)

Poisons Act 1964 (Western Australia)

Medicines, Poisons and Therapeutic Goods Act 2012 (Northern Territory)

Poisons and Therapeutic Goods Act 1966 (New South Wales)

Poisons and Therapeutic Goods Regulation 2008 (New South Wales)

Poisons (Declared Restricted Substances) Order 1990 (Tasmania)
http://www.legislation.tas.gov.au/tocview/index.w3p;cond=;doc_id=%2B189%2B1990%2BAT%40EN%2B20140403000000;histon=;prompt=;rec=;term=
Poisons List Order 2001 (Tasmania)

Poisons Regulations 1965 (Western Australia)

Poisons Regulations 2008 (Tasmania)
