



## OPERATIONAL DIRECTIVE

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**Subject:** **Vaccine Cold Chain Guidelines**

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This document contains policies and guidelines for monitoring and maintaining the cold chain process.

The “cold chain” is a system of transporting and storing vaccines within a recommended temperature range of +2 to +8 degrees Celsius (°C). This temperature range has been selected by the World Health Organization (WHO), and adopted by the Australian Technical Advisory Group on Immunisation (ATAGI) for the National Immunisation Program (NIP), as a guide to protect vaccines against loss of vaccine potency due to excessive cold or heat<sup>1</sup>.

The policies and guidelines contained within this document apply to all Western Australian (WA) public and community health services providing immunisation services in WA.

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**DIRECTOR GENERAL**  
**DEPARTMENT OF HEALTH WA**

**This information is available in alternative formats upon request.**

## 1. Scope

This document contains policies and guidelines that apply to all Western Australian (WA) Public and Community Health Services providing immunisation services in WA.

## 2. The cold chain

The “cold chain” is a system of transporting and storing vaccines within a recommended temperature range of +2 to +8 degrees Celsius (°C). This temperature range has been selected by the World Health Organization (WHO), and adopted by the Australian Technical Advisory Group on Immunisation (ATAGI) for the National Immunisation Program (NIP), as a guide to protect vaccines against loss of vaccine potency due to excessive cold or heat<sup>1</sup>.

The Communicable Disease Control Directorate (CDCD), Department of Health, Western Australia, is committed to best practice standards in the shipment, storage and administration of vaccines. The recommended standards outlined in this policy document are drawn from the current edition of the *Australian Immunisation Handbook*<sup>2</sup>, the *National Vaccine Storage Guidelines – Strive for Five (2005)*<sup>3</sup> and the current *Western Australian Drugs and Poisons Regulations*<sup>4</sup>. For further information on maintaining the cold chain process, consult these publications.

Every immunisation service provider (ISP) should have access to a copy of the current edition of the *Australian Immunisation Handbook*<sup>2</sup>, along with the *National Vaccine Storage Guidelines - Strive for Five*<sup>3</sup>, the *Cold Chain Action Plan* and the *Daily Vaccine Fridge Temperature Recordings Calendar* (all on-line at: [http://www.public.health.wa.gov.au/3/471/2/cold\\_chain\\_immunisation.pm](http://www.public.health.wa.gov.au/3/471/2/cold_chain_immunisation.pm)). These documents should be referred to for best practice guidelines.

The Australian Government provides Western Australia with over \$30 million of vaccines under the NIP. It is the responsibility of CDCD, Child and Adolescent Community Health (CACH), the public health units (PHU) and all ISPs to monitor, review and implement the processes in place to maintain the efficacy of these vaccines and minimise wastage.

## 3. Recommendations for monitoring and maintaining the cold chain process

WA ISPs are required to adopt and adhere to the recommendations set out below for monitoring and maintaining the cold chain process.

### 3.1. Vaccines during transport

- The WA Department of Health contracts a commercial logistics company to distribute vaccines around the State from a central distribution warehouse based in Perth. In the metropolitan area vaccine shipments are made directly from the State Distribution Centre to ISPs. In regional areas, the State Distribution Centre ships vaccines to the regional pharmacies who act as Regional Distribution Centres by on-forwarding vaccines to ISPs within their region.
- Vaccines should be transported in refrigerated, temperature-monitored vehicles or in portable insulated containers (esbies) in order to maintain vaccine immunogenicity as described in the *National Vaccine Storage Guidelines – Strive for Five*<sup>3</sup>.
- When using esbies to transport vaccines, esbies must be packed and ice bricks sweated according to *National Vaccine Storage Guidelines – Strive for Five*<sup>3</sup>.

- The State Distribution Centres must use cold chain monitors or data loggers when transporting vaccines, as recommended in the *National Vaccine Storage Guidelines – Strive for Five*.<sup>3</sup>
- Regional Distribution Centres should use cold chain monitors, minimum/maximum thermometers or data loggers when sending vaccines to ISPs in their regions, as recommended in the *National Vaccine Storage Guidelines – Strive for Five*.<sup>3</sup>
- Out-reach clinics should use minimum/maximum thermometers, data loggers or cold chain monitors when transporting vaccines in eskies.
- On receipt of vaccine shipments, ISPs should check the cold chain monitor to ensure the vaccines are within the +2° to +8°C range. In the metropolitan area, if the cold chain monitor indicates the vaccines fall outside this range, the delivery should be refused and the State Distribution Centre should be informed immediately. In regional areas, if vaccines fall outside the +2° to +8°C range during forward transportation from the Regional Distribution Centre, the Regional Distribution Centre must be informed of the breach and the regional immunisation coordinator (RIC) should be contacted for advice on the efficacy of the vaccines.

### 3.2. Vaccines in the refrigerator

- Where possible, vaccines should be stored in a vaccine-specific refrigerator. Bar fridges are unsuitable for storing vaccines and cyclic defrost fridges are not recommended.
- The refrigerator temperature should be checked and recorded twice daily on the *Daily Vaccine Fridge Temperature Recordings Calendar* (available from the Public health website [http://www.public.health.wa.gov.au/3/471/2/cold\\_chain\\_\\_immunisation.pm](http://www.public.health.wa.gov.au/3/471/2/cold_chain__immunisation.pm)). Notable changes in temperature ranges should be discussed with your RIC.
- Accurate determination of the refrigerator temperature is important as deviations outside the recommended +2° to +8°C range can affect the efficacy of vaccines. ISPs are strongly encouraged to have a data logger installed in their vaccine refrigerator. Data from the data logger should be downloaded and reviewed weekly.
- A back-up minimum/maximum thermometer or data logger in the refrigerator is recommended. This will enable the refrigerator temperature to be assessed in the event of a power outage that may result in reduced vaccine wastage. In addition, a back-up thermometer or data logger provides an alternate reading in case of battery or technical failure of your primary thermometer.
- In unusual circumstances where vaccines are stored in refrigerators in buildings which are not accessed daily, data loggers must be installed and they need to be read weekly. Minimal vaccine stocks should be stored in refrigerators that are not regularly accessed.

### 3.3. Vaccine management

- Vaccine management is the responsibility of all staff. It is important that more than one staff member is educated on how to appropriately store vaccines, read and record daily refrigerator temperatures and reset data loggers and vaccine refrigerator monitors.
- Management of a new vaccine refrigerator – All newly installed vaccine refrigerators need to be monitored continuously with a data logger for at least 48 hours prior to use to ensure the refrigerator has a stable reading within the recommended range of +2° to +8°C.

- Ongoing management of a vaccine refrigerator – To ensure optimal functionality, the vaccine refrigerator should be continuously monitored for 48 hours with a data logger at least once annually. If the refrigerator cannot maintain a temperature range of +2 to +8°C it should be serviced or decommissioned.
- Vaccine refrigerators should be serviced as per the manufacturer's guidelines. Documentation of the service should be retained by the provider.
- Vaccine management is considered a key performance indicator for GP accreditation. Records of daily temperature readouts, weekly data logger readouts and annual refrigerator audits should be kept for accreditation purposes.

### 3.4. Ordering vaccines

- Government-procured vaccines can be ordered from CDCD via the on-line ordering website (<http://colors.csldirect.com.au/>). Those without internet access may order by fax on 9388 4877. A vaccine order form can be obtained from the Public Health website at:  
[http://www.public.health.wa.gov.au/3/473/2/provider\\_information\\_\\_immunisation.pm](http://www.public.health.wa.gov.au/3/473/2/provider_information__immunisation.pm).
- When placing a vaccine order, 'stock on hand' (i.e. the vaccines currently in the ISPs refrigerator) must be recorded in the appropriate column of the ordering sheet. This is a compulsory field and without this information the order cannot be processed.
- On receiving new stock, ensure vaccines closest to expiration are stored at the front of the refrigerator. Vaccines that have passed the 'expiry date' need to be disposed of and the wastage reported to the RIC using the *Vaccine Wastage Report Form* (Appendix C, and on-line at:  
[http://www.public.health.wa.gov.au/3/471/2/cold\\_chain\\_\\_immunisation.pm](http://www.public.health.wa.gov.au/3/471/2/cold_chain__immunisation.pm)).
- Order and maintain appropriate levels of stock to meet the needs of clinic/practice while ensuring the refrigerator is not overcrowded. Stockpiling large quantities of vaccines is strongly discouraged as this poses a greater risk of substantial loss in the event of a refrigerator failure or power outage.
- A vaccine storage self-audit should be undertaken by the clinic/practice every six months, as recommended in the *National Vaccine Storage Guidelines – Strive for Five*<sup>3</sup>. An audit template is included in Appendix 1 of the Strive for Five document which can be downloaded from:  
<http://immunise.health.gov.au/internet/immunise/publishing.nsf/Content/provider-store>

## 4. Cold chain breach

The cold chain is a shared responsibility that begins from the time the vaccine is manufactured, and ends when the vaccine is administered to the recipient. A cold chain breach (CCB) occurs when the temperature falls outside of the recommended +2° to +8°C temperature range at any point during the cold chain process. Common breaks in the cold chain occur through refrigeration failure, power outage, overheating of vaccines during transportation, and freezing of vaccines.

Temperature variations outside the +2° to +8°C temperature range can result in loss of efficacy to the vaccine. It is therefore imperative that all CCBs be reported to the RIC using the reporting process for a CCB, as outlined in section 4.1.

#### 4.1. Process for reporting a cold chain breach (CCB)

- See Appendix A for a flow chart of the reporting process.
- Following a CCB, ISPs should isolate the affected vaccines by moving them to an alternate +2 to +8°C location and marking the vaccines clearly with 'Do Not Use'. The ISP should complete the check list on page 2 of the Cold Chain Incident Report Form (Appendix B, also on-line at [http://www.public.health.wa.gov.au/3/471/2/cold\\_chain\\_immunisation.pm](http://www.public.health.wa.gov.au/3/471/2/cold_chain_immunisation.pm)) and fax the form to the RIC. The ISP should then telephone the RIC for follow-up advice. The RIC will provide advice around the use or disposal of vaccines affected by the breach. ISPs should not discard any vaccines until authorised to do so by the RIC.
- On receipt of the Cold Chain Incident Report Form, the RIC will take the steps outlined in Table 1 in order to maintain efficacy of the vaccines, reduce, where possible, unnecessary wastage of vaccines, and support the education and ongoing involvement of the ISP in safe, effective immunisation delivery.

**Table 1: Role of the Regional Immunisation Coordinator following a Cold Chain Breach**

<b>RIC Action following a Cold Chain Breach (CCB)</b>	
1.	Ask the ISP to safely store the affected vaccines in an alternate +2° to +8°C environment and clearly labelled them 'Do Not Use.'
2.	Obtain full details of the temperatures reached and the duration for which the vaccines were outside the +2° to +8°C range.
3.	Request the ISP completes a <b>Cold Chain Incident Report Form</b> (Appendix B, and on-line at <a href="http://www.public.health.wa.gov.au/3/471/2/cold_chain_immunisation.pm">http://www.public.health.wa.gov.au/3/471/2/cold_chain_immunisation.pm</a> )
4.	Consult the <b>Temperature Sensitivity of Vaccines Table*</b> for advice on the efficacy of the affected vaccines. Contact CDCD or the relevant vaccine manufacturer for vaccines or circumstances not listed in the temperature sensitivity table.
5.	Provide written advice to the ISP on the recommended course of action for each vaccine affected by the CCB.
6.	If appropriate, request the affected refrigerator and temperature monitors are replaced or serviced <u>prior to</u> the ISP placing an order to re-stock their vaccines.
7.	Alert the vaccine orders team at CDCD of any CCB resulting in significant wastage of vaccines ( <a href="mailto:vaccineorders@health.wa.gov.au">vaccineorders@health.wa.gov.au</a> ). This will facilitate the approval process of replacement orders for ISPs who have lost their stock.
8.	Request the ISP provide a full record of vaccine wastage resulting from the CCB using the <b>Vaccine Wastage Report Form</b> (Appendix C). Note that this may occur several times over the next few months as stock with shortened shelf life expires.
9.	Review the processes undertaken by the ISP in this cold chain event and, if needed, provide education to minimise vaccine loss associated with future CCBs.
10.	Consider if a subsequent review of the ISP practice is needed to ensure that the cold chain storage complies with the recommended guidelines. If needed, this review may be referred to a Division Immunisation Project Officer (DIPO), CACH or RIC for follow-up.

**\*Note:** the **Temperature Sensitivity of Vaccines Table\*** is for RIC use only. The table has been developed by the WA Department of Health and is predominantly based on the WHO *Temperature Sensitivity of Vaccines' 2006 guidelines*<sup>1</sup> and a number of other published sources. The National Immunisation Committee has a Working Group tasked with compiling national guidelines around the temperature sensitivity of vaccines used on the National Immunisation Program. When the Working Group's guidelines become available they will replace the WA Department of Health temperature sensitivity of vaccines table.

## 4.2. Role of CDCD following a cold chain breach

- Following a CCB, CDCD can assist the RIC and ISP in a number of ways, as detailed in Table 2 below.

**Table 2: Role of the Communicable Disease Control Directorate in supporting RICs and ISPs following a Cold chain breach**

CDCD Action following a Cold Chain breach (CCB)	
1.	If adequate information on vaccine efficacy is not available from the <b>Temperature Sensitivity of Vaccines Table</b> , CDCD will seek information from vaccine supply companies and/or relevant vaccine experts on a case by case basis. Findings will be reported back to the RIC to guide their feedback to the ISP
2.	Where needed, CDCD will provide advice on revaccination to RICs and public health physicians through consultation with immunisation experts (see section 4.3)

## 4.3. Re-vaccination following a cold chain breach

- The need to recall patients for revaccination following a CCB is rare. If re-vaccination is necessary, it will be undertaken by the ISP in consultation with the RIC and an immunisation expert. Where needed, CDCD will provide advice through consultation with immunologists and vaccine experts. To facilitate timely advice, a detailed list including patient name, date of birth, and vaccination history should be prepared by the ISP and forwarded to the RIC. CDCD should be notified of all complex or large scale revaccinations.
- National guidelines for re-vaccination have been developed by a Working Party of the National Immunisation Committee and ratified by the Australian Technical Advisory Group on Immunisation Compromised Vaccine Guidelines 2011. These guidelines are intended for use by jurisdictional immunisation coordinators to facilitate the provision of best practice advice to ISPs. These guidelines have been distributed by CDCD to RICs throughout the State.

## 5. Vaccine efficacy following a cold chain breach

Vaccines are delicate biological substances that can become less effective or destroyed if they are frozen, allowed to get too hot and/or exposed to direct sunlight or fluorescent light.

### 5.1. Freezing

- Freezing of vaccine is the most common reason for vaccine damage and loss in Australia. For vaccines that are cold or freeze-sensitive, the loss of potency following freezing is immediate and these vaccines must not be administered. There are some exceptions to this rule, such as those vaccines in their dried form that are stable below 0°C and are not damaged by freezing<sup>2</sup>.
- In all instances where vaccines are exposed to temperatures outside the recommended +2° to +8°C temperature range, ISPs are required to contact the RIC for advice on vaccine efficacy.

### 5.2. Heat

- Freezing is a greater danger to vaccine efficacy than mild heat exposure<sup>2</sup>. Heat impact on vaccines is cumulative, therefore, vaccines exposed to temperature ranges over +8°C will, in some instances, still be able to be administered but may have a shortened shelf life as a result of the heat exposure. When vaccines are exposed to

repeated episodes of heat, the loss of vaccine potency is cumulative and cannot be reversed.

- In all instances where vaccines are exposed to temperatures outside the recommended +2° to +8°C temperature range, ISPs are required to contact the RIC for advice on vaccine efficacy.

### 5.3. Accuracy of temperature measurement

- An accurate reading of temperature is essential in order to determine a vaccine's efficacy following an excursion outside the recommended +2° to +8° C temperature range. All immunisation service providers (ISPs) need to know the accuracy of the equipment they are using to measure temperature in their refrigerator. A standard min/max thermometer (with a single digit display) usually has an error margin of  $\pm 1^\circ\text{C}$ . In contrast, data loggers can have an error margin of  $\pm 0.5^\circ\text{C}$  or less. Most vaccines are irreversibly damaged when they freeze, therefore, the ability to accurately and confidently measure  $0^\circ\text{C}$  within your refrigerator will determine whether the vaccines can be kept following a cold chain breach (CCB) between the range of  $0^\circ$  to  $+2^\circ\text{C}$ .
- ISPs are strongly encouraged to have data loggers within their refrigerator which will enable a detailed picture of the temperature excursions during a CCB to be examined and potentially hundreds of dollars worth of vaccines to be saved. In addition, ISPs are encouraged to know the accuracy of the equipment within their refrigerator and to check the calibration annually. For advice on calibration of data loggers, refer to the manufacturers' directions. For advice on calibration of min/max thermometers, follow the steps described in the National vaccine Storage Guidelines – Strive for Five<sup>3</sup> (<http://immunise.health.gov.au/internet/immunise/publishing.nsf/Content/provider-store>).

## 6. Vaccine wastage

Vaccine wastage occurs as a result of many factors including refrigerator failure, power outages, CCBs during transportation, breakage, vaccine expiry, or administering the wrong dose or incorrect vaccine to an individual.

Reporting of vaccine wastage is a requirement of the vaccine procurement contract with the Australian Government and is done on a quarterly basis. This data is used to inform the National Immunisation Program of vaccine wastage under the current National Partnership Agreement for Essential Vaccines (NPAEV). Vaccines wasted through natural disasters, power outages and refrigeration failure (i.e. events beyond human control) are taken into account by the Commonwealth when calculating the wastage incurred by each State and Territory. Reduction of vaccine wastage is a performance indicator under the NPAEV and is tied to additional payments which are used to run State-funded vaccination programs. To provide accountability and maximise WA's opportunity to meet the performance benchmark, it is important to document all vaccine wastage and the circumstances in which the wastage came about.

ISPs are required to document vaccine wastage as it occurs and report it to their RIC using the *Vaccine Wastage Report Form* (Appendix C, also available on-line at [http://www.public.health.wa.gov.au/3/471/2/cold\\_chain\\_\\_immunisation.pm](http://www.public.health.wa.gov.au/3/471/2/cold_chain__immunisation.pm)). This form can be used to report all wastage, regardless of whether or not the wastage resulted from a CCB. The report should be faxed or emailed to the RIC using contact details on the bottom of the form.

RICs are required to collate the vaccine wastage reports received from ISPs within their area on a quarterly basis at the end of March, June, September and December of each year using the *Quarterly Wastage Report Form*. RICs can download the report form from

the Public Health website:

([http://www.public.health.wa.gov.au/3/471/2/cold\\_chain\\_\\_immunisation.pm](http://www.public.health.wa.gov.au/3/471/2/cold_chain__immunisation.pm)). Reports should be faxed or emailed to CDCD within five working days of the end of each quarter.

### **6.1. Vaccine disposal**

- Vaccines that need to be destroyed should be disposed of according to the medical waste disposal procedures operating within the practice/clinic.

## **7. Conclusion**

All vaccine service providers play a vital role in maintenance of the cold chain to ensure the efficacy and safety of vaccines administered. Maintaining cold chain standards is vital given the large number of vaccines now stored within each practice/clinic and the cost attached to these vaccines.

CDCD is working closely with the RICs, Child and Adolescent Community Health, the local government authorities and General Practice to ensure all ISPs are consistently working within the recommended standards of practice.

ISPs are required to use the cold chain protocols provided by CDCD, the *National Guidelines for Vaccine Storage - Strive for 5<sup>3</sup>* and the current edition of the *Australian Immunisation Handbook<sup>2</sup>* in order to provide correct and consistent cold chain monitoring.

When a cold chain breach results in vaccine loss, accurate wastage reporting is essential as it is a requirement of the NPAEV and is crucial for WA to meet the nationally set performance benchmarks.



## References

1. World Health Organization (2006). Temperature sensitivity of vaccines. View this reference at <http://www.who.int/vaccines-documents/DocsPDF06/847.pdf>
2. National Health and Medical Research Council (2008). The Australian Immunisation Handbook 9<sup>th</sup> Ed. Commonwealth of Australia. View this reference at <http://immunise.health.gov.au/internet/immunise/publishing.nsf/Content/handbook-home>
3. Australian Government Department of Health and Ageing (2005). National Storage Guidelines. Strive for Five. Commonwealth of Australia. View this reference at <http://immunise.health.gov.au/internet/immunise/publishing.nsf/Content/provider-store>
4. Poisons Act – Regulations 1965 (WA) and the Poisons Amendment Regulations 2010 (WA). View this reference at [http://www.public.health.wa.gov.au/1/872/2/pharmaceutical\\_services.pm](http://www.public.health.wa.gov.au/1/872/2/pharmaceutical_services.pm)

## Appendices - for use by immunisation service providers

Appendix A: Cold Chain Breach (CCB) protocol flow chart

Appendix B: Cold Chain Incident Report Form  
([http://www.public.health.wa.gov.au/3/471/2/cold\\_chain\\_immunisation.pm](http://www.public.health.wa.gov.au/3/471/2/cold_chain_immunisation.pm))

Appendix C: Vaccine Wastage Report Form for Immunisation Service Providers  
([http://www.public.health.wa.gov.au/3/471/2/cold\\_chain\\_immunisation.pm](http://www.public.health.wa.gov.au/3/471/2/cold_chain_immunisation.pm))

## Abbreviations

<b>°C</b>	Degrees celsius
<b>ATAGI</b>	Australian Technical Advisory Group on Immunisation
<b>CACH</b>	Child and Adolescent Community Health
<b>CCB</b>	Cold chain breach
<b>CDCD</b>	Communicable Disease Control Directorate
<b>DIPO</b>	Division immunisation project officer (General Practice)
<b>DoH</b>	Department of Health
<b>GP</b>	General practice
<b>ISP</b>	Immunisation service provider
<b>NIP</b>	National Immunisation Program
<b>NPAEV</b>	National Partnership Agreement on Essential Vaccines
<b>OP</b>	Operational Procedure
<b>PHU</b>	Public health unit
<b>RIC</b>	Regional immunisation coordinator – <i>designated Public Health Unit professional who promotes immunisation and responds to vaccine issues in their Area Health Service</i>
<b>WA</b>	Western Australia
<b>WHO</b>	World Health Organization

## Cold Chain Breach (CCB) Protocol Flow Chart

### Immunisation Service Providers

1. Isolate all vaccines involved in the CCB in an alternate +2° to +8°C location. Clearly mark the vaccine with 'do not use'.

2. Assess the temperature the fridge reached and the length of time the temperature was out of the +2° to +8°C range. If a data logger was present an immediate read out should be undertaken.

3. Record the type and number of vaccines involved in the CCB using the Cold Chain Incident report form for Government-funded vaccines.

4. Contact the RIC to report the CCB and seek advice on vaccine efficacy. Do NOT discard any vaccines prior to contacting the RIC.

5. Shorten the shelf life or destroy affected vaccines, as advised by the RIC. Destroyed vaccines should be disposed of using your standard medical waste procedures.

6. Report all vaccine wastage to the RIC. This may occur more than once following a CCB, depending on the advice given by the RIC for shortening the shelf life of affected vaccines.

7. Conduct a patient recall if revaccination is deemed necessary after consultation with the RIC.

### Regional Immunisation Coordinator

1. Ask ISP to move all vaccines involved in the CCB to an alternate +2° to +8°C location and clearly mark the vaccines with 'do not use'.

2. Obtain full details of the temperature reached and the duration for which the vaccines were outside the +2° to +8°C range.

3. Request the ISP completes and forwards to you a Cold Chain Incident report form for Government-funded vaccines.

4. Provide the ISP with written advice on the efficacy of the affected vaccines and coordinate the follow up action, including revaccination if necessary. Advice can be sought from CDCD as required.

5. If appropriate, request the affected fridge and temperature monitors are replaced or serviced prior to the ISP restocking their fridge.

6. Request full details of all vaccines destroyed by the ISP as a result of the CCB. Include this wastage in your next quarterly wastage report to CDCD.

7. Review the processes undertaken by the ISP in this CCB. If you have concerns about the vaccine storage equipment or cold chain knowledge of the ISP, refer the ISP to a DIPO / CACHS / RIC for subsequent follow up.

## Cold Chain Incident Report Form

### Government-funded vaccines

(available on-line at [http://www.public.health.wa.gov.au/3/471/2/cold\\_chain\\_immunisation.pm](http://www.public.health.wa.gov.au/3/471/2/cold_chain_immunisation.pm))

Complete the Cold Chain Breach Incident Checklist on the following page prior to contacting your **Regional Immunisation Coordinator (RIC)** for advice.

**FAX** both pages of this form to the RIC in your area (see RIC contact details on next page).

RIC Name: \_\_\_\_\_ Public health unit: \_\_\_\_\_  
 RIC Fax No: \_\_\_\_\_ RIC Telephone No: \_\_\_\_\_

Report the **number of government-funded vaccines** involved in the cold chain incident in the table below. Do not discard any of these vaccines before discussing the incident with your RIC.

Adacel (dTpa)	Gardasil (HPV)	HBVax-II (Adult)	HBVax-II (Paed)	Hiberix (Hib)	Infanrix Hexa	Ipol (IPV)	Neisvac (MenCCV)	Pneumovax (23vPPV)	Prevenar (13vPCV)
Priorix (MMR)	Quadracel (DTPa-IPV)	Rotateq (ORV)	Twinrix (HepA/B)	Vaqta (HepA)	Varilrix (VZV)	Fluvax	Influvac	Vaxigrip	Vaxigrip Jnr

**Other vaccine** (not listed above): \_\_\_\_\_

**Date of Incident:** \_\_\_\_\_ **Name of Notifier:** \_\_\_\_\_

**Location/Address of Cold Chain Incident:** \_\_\_\_\_

**Phone:** \_\_\_\_\_ **Fax:** \_\_\_\_\_ **Email:** \_\_\_\_\_

**Type of Incident:** fridge failure  power outage  transport issue  vaccine expiry  other

**Description of Incident:** \_\_\_\_\_

**Actions undertaken by practice/clinic reporting incident:** \_\_\_\_\_

**Further recommended actions from the RIC:** \_\_\_\_\_

**Signed (notifier):** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Signed (RIC):** \_\_\_\_\_ **Date:** \_\_\_\_\_

## Cold Chain Incident Report Form (continued)

### Government-funded vaccines

(available on-line at [http://www.public.health.wa.gov.au/3/471/2/cold\\_chain\\_immunisation.pm](http://www.public.health.wa.gov.au/3/471/2/cold_chain_immunisation.pm))

### COLD CHAIN BREACH (CCB) INCIDENT CHECK LIST

Follow steps 1-6 and complete the table below **prior** to contacting your **Regional Immunisation Coordinator (RIC)**. See RIC contact list at the bottom of this page for details of your nearest RIC.

1. Isolate the vaccines in a **+2°C to +8°C** environment and clearly label 'do not use.'
2. Record the type and number of vaccines involved in the CCB, using the table on the previous page.
3. Contact your RIC as soon as possible, see contact details below.
4. Do not discard any vaccines until advice has been sought from your RIC.
5. Take active steps to correct and prevent the problem recurring.

Date of the breach	
What were the minimum and maximum temperature readings?	
What was the reading when the breach was noticed?	
How long was the temperature outside +2°C to +8°C?	
When was the thermometer last reset?	
When was the battery in the thermometer last changed?	
When was the accuracy of the thermometer last checked?	
How long do you think these problems have been occurring?	
Where is the temperature probe situated?	
Where are the vaccines stored in the refrigerator?	
Have any vaccines been pushed up against the cooling plate or a cold air outlet?	
What is the expiry date of the vaccines?	
Are the vaccines in their original packaging?	
Are the vaccines kept in a domestic refrigerator?	
If using a domestic refrigerator, are there water bottles in the doors, unused shelves and drawers?	
Does the refrigerator have a designated power source?	
Does the refrigerator have an alarm fitted?	
What do you think was the cause of the CCB?	
Has the cause of the CCB been rectified?	
Has anybody been vaccinated with potentially affected vaccines?	

### REGIONAL IMMUNISATION COORDINATOR (RIC) CONTACT LIST

<b>Lower North Metro</b>	<b>Upper North Metro</b>	<b>South Metro</b>	<b>Wheatbelt</b>	<b>Goldfields</b>	<b>Great Southern</b>
Tel: 9380 7746	Tel: 9380 7745	Tel: 9431 0217	Tel: 9622 4320	Tel: 9080 8200	Tel: 9842 7500
Fax: 9380 7751	Fax: 9380 7736	Fax: 9431 0223	Fax: 9622 5752	Fax: 9080 8202	Fax: 9842 7534
<b>Kimberley</b>	<b>Midwest</b>	<b>Carnarvon</b>	<b>Pilbara</b>	<b>South West</b>	
Tel: 9194 1643	Tel: 9956 1964	Tel: 9941 0519	Tel: 9158 9207	Tel: 9781 2355	
Fax: 9194 1631	Fax: 9956 1991	Fax: 9941 0520	Fax: 9158 9220	Fax: 9781 2382	

## Vaccine Wastage Report Form for Immunisation Service Providers

### Government-funded vaccines

(available on-line at [http://www.public.health.wa.gov.au/3/471/2/cold\\_chain\\_immunisation.pm](http://www.public.health.wa.gov.au/3/471/2/cold_chain_immunisation.pm))

Immunisation Service Providers must report **all wastage of government-funded vaccines** as it occurs within their practice/clinic. Please enter **the number** of government-funded vaccines wasted and destroyed in the chart and fax the form to your RIC, using the contact details below.

**Date of disposal:** \_\_\_\_\_ **Date of Cold Chain Event** (if applicable): \_\_\_\_\_

VACCINE	Fridge failure	Power outage	Vaccine expiry	Other (specify)
Adacel (dTpa)				
Gardasil (HPV)				
HBVax-II Adult (Hep B)				
HBVax-II Paediatric (Hep B)				
Hiberix (Hib)				
Infanrix Hexa (DTPa-hepB-IPV-Hib)				
Ipol (IPV)				
Neisvac-C (MenCCV)				
Pneumovax 23 (23vPPV)				
Prevenar 13 (13vPCV)				
Priorix (MMR)				
Quadracel (DTPa-IPV)				
RotaTeq (ORV <sup>1</sup> )				
Twinrix (HepA-HepB)				
Vaqta (Hep A)				
Varilrix (VZV)				
Fluvax (Influenza)				
Influvac (Influenza)				
Vaxigrip (Influenza)				
Vaxigrip Junior (Influenza)				
Other: _____				
Other: _____				
<b>Total</b>				

**Name of Practice/Clinic:** \_\_\_\_\_

**Name of contact person:** \_\_\_\_\_

**Phone:** \_\_\_\_\_ **Fax:** \_\_\_\_\_ **Email:** \_\_\_\_\_

### REGIONAL IMMUNISATION COORDINATOR (RIC) CONTACT LIST

<b>Lower North Metro</b>	<b>Upper North Metro</b>	<b>South Metro</b>	<b>Wheatbelt</b>	<b>Goldfields</b>	<b>Great Southern</b>
Tel: 9380 7746	Tel: 9380 7745	Tel: 9431 0217	Tel: 9622 4320	Tel: 9080 8200	Tel: 9842 7500
Fax: 9380 7751	Fax: 9380 7736	Fax: 9431 0223	Fax: 9622 5752	Fax: 9080 8202	Fax: 9842 7534
<b>Kimberley</b>	<b>Midwest</b>	<b>Carnarvon</b>	<b>Pilbara</b>	<b>South West</b>	
Tel: 9194 1643	Tel: 9956 1964	Tel: 9941 0519	Tel: 9158 9207	Tel: 9781 2355	
Fax: 9194 1631	Fax: 9956 1991	Fax: 9941 0520	Fax: 9158 9220	Fax: 9781 2382	