



PROCEDURE

Reconstitution of Vaccines – Meningococcal ACWY at a Mass Immunisation Clinic

Scope (Staff):	Community health staff
Scope (Area):	CACH

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this [disclaimer](#)

Aim

To reconstitute vaccines safely in accordance with the vaccine manufacturer's specifications and the [Australian Commission on Safety and Quality in Health Care's Medication Safety Standard 4](#), and to ensure that reconstituted vaccines are stored appropriately according to the [National vaccine storage guidelines: Strive for 5](#).

Risk

Incorrect vaccine reconstitution will expose clients to the risk of a vaccine preventable disease with potentially serious consequences, as well as possible medication related adverse side effects.

Background

- Immunisation is the safest and most effective way to protect children and the wider community from vaccine-preventable diseases. The delivery of the [Western Australian Immunisation Schedule](#) forms part of an overall strategy to reduce the burden of vaccine preventable diseases within the community.
- The [Australian Immunisation Handbook](#) provides current clinical guidelines for health professionals on the safest and most effective use of vaccines in their practice.
- Vaccine administration must occur in accordance with a structured Administration and Supply Arrangement (SASA). The WA SASA for the [Administration of Vaccines by Registered Nurses](#) states the requirements for registered nurses to be eligible to administer vaccines. These include a list of vaccines that can be

administered, and approved training courses that are required to be completed to reach and maintain competency.

Key points

- The [5 Moments for Hand Hygiene](#) (as per the [National Hand Hygiene Initiative](#)) are adhered to throughout the procedure.
- Nurse responsible for vaccine monitoring and packaging is clearly delegated.
- The vaccine vial + prefilled diluent syringe are counted and recorded prior to leaving the immunisation base at the beginning of the day. Prior to leaving the school/after the session, empty vaccine vials are reconciled ensuring that the number of vaccines reconstituted equals the number of consents obtained for the given vaccines. Vaccine refusals and wastage must be accounted for in this reconciliation.
- If multiple syringes are required, they must be prepared, labelled and administered sequentially as independent operations (groups of 10 or 20 at a time).
- This procedure is to be used in conjunction with the [Immunisation – Childhood](#).
- This procedure can be adapted to any other vaccine needing reconstitution at individual level.
- Both the medication administrator and independent second checker are equally responsible for the correct administration of medication according to the [Six Rights of Safe Medication Administration in Immunisation](#).
- Any medicine or fluid that cannot be identified is to be considered unsafe and discarded immediately. See [Labelling of Injectable Medications and Fluids](#).

Equipment



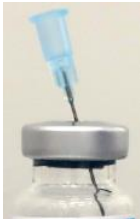
- Sharps Container
- Esky/cooler
- 23G 1 ¼” BD Hypodermic blue needle (for drawing up vaccine and diluents)
- 23G 1” Magellan Safety needles (for administration of vaccine)
- Universal disinfectant wipes (to wipe down and clean surfaces)
- Alcohol-based hand rub (ABHR) for hand hygiene (not for skin prep at vaccination site. No skin prep needed to clean administration site)
- Plastic bin bag
- White bib
- Labels (vaccine vial [powder] has x2 product labels from manufacturer that are sufficient)

- Vaccine vial (powder) to be reconstituted
- Diluent in prefilled syringe to reconstitute vaccine powder and labelled with product label
- Pen to record number of vaccines removed from esky/cooler
- [School Based Immunisation: Vaccine Management Nurse Daily Record Form \(CHS516\)](#) to record:
 - Cold chain storage temperatures hourly
 - Number of vaccines taken to and from the vaccination site
 - Time esky accessed to take out pre-determined number of vaccine powder vials and diluent syringes
- “DO NOT DISTURB” – sign.

Procedure

Steps	Additional Information
<p>1. Clear designation of roles</p> <ul style="list-style-type: none"> • Discuss allocated duties for the day. <ul style="list-style-type: none"> ○ This must be done at the base <u>or</u> on arrival at the school if the nurses are meeting at the site. • Reinforce the vaccine ‘reconstitution zone’ as an interruption-free area. <ul style="list-style-type: none"> ○ Display the “DO NOT DISTURB” sign to all staff, advising that no talking is to occur close to the nurse stationed in this area. 	<ul style="list-style-type: none"> • Ensuring staff are aware of their roles will allow for efficiency and safe work processes. • Provide information on who to contact for assistance, when needed. • It is essential to reduce the risk of distraction for the nurse reconstituting vaccines. <ul style="list-style-type: none"> ○ Other nurses will wait for delivery of the reconstituted vaccines at their stations and any questions will be answered by a team leader. ○ The “DO NOT DISTURB” sign provides a visual reminder to nurses and the Department of Education staff that this staff member must not be interrupted.
<p>2. Preparation</p> <p><u>Room set-up:</u></p> <ul style="list-style-type: none"> • The drawing up workspace must be separate from immunisation 	<ul style="list-style-type: none"> • Reduces the risk of distractions but ensures the nurse is not isolated.

Steps	Additional Information
<p>stations but within sight of the team.</p> <ul style="list-style-type: none"> • Clean area/table with universal disinfectant wipes and allow to dry. <p><u>Equipment set-up:</u></p> <ul style="list-style-type: none"> ○ White bib placed on clean area ○ Open sharps container on table/desk ○ Nimenrix powder vials and diluent syringe in the portable esky/cooler ○ Bag of 23G 1 ¼” BD Hypodermic blue needles ○ 23G 1” Magellan Safety needles ○ Attach rubbish bag to desk. <ul style="list-style-type: none"> • Check and record temperature hourly on School Based Immunisation: Vaccine Management Nurse Daily Record Form (CHS516). 	<ul style="list-style-type: none"> • For more information, see National vaccine storage guidelines: Strive for 5.
<p>3. Reconstitution</p> <ul style="list-style-type: none"> • Clean hands with ABHR and allow to dry. • Remove 10 Nimenrix powder vials and 10 diluent syringes and place onto cleaned area. • Check the expiry dates on the Nimenrix vial/diluent. • Prepare one Nimenrix vial and one diluent at a time. • Clean hands with ABHR and allow to dry. • Remove brown cap from Nimenrix vial. 	<ul style="list-style-type: none"> • Must be equal amounts (i.e. same number of diluents and Nimenrix vials). • Vaccine can remain at room temperature during this reconstitution process. • Maintain infection control by not touching the surface of opened vial. • Leaving the needle in the vial is a visual cue that this vial is empty. This will assist in the reconciliation of vaccines.

Steps	Additional Information
<ul style="list-style-type: none"> • Peel off the 2 vial stickers (as shown below) ready to place on diluent syringe.  <ul style="list-style-type: none"> • Partially open packaging containing blue 23G 1 ¼" BD Hypodermic blue (drawing up) needles. <ul style="list-style-type: none"> ○ Retain this needle within its packaging (as shown below) and place onto cleaned surface.  <ul style="list-style-type: none"> • Remove the bung from diluent syringe and attach the blue drawing up needle (in above point) to the syringe. • Insert diluent syringe into centre of Nimenrix vial and add the entire contents of the syringe to the vial. Mix gently until the powder is completely dissolved. DO NOT SHAKE THE VIAL. • Carefully draw up the contents of the vial into the syringe and then separate the syringe from the needle, leaving the drawing-up needle in the empty vial (as shown below). 	

Steps	Additional Information
<p>4. Prior to distribution</p> <p>Reconstituting nurse + 1 RN:</p> <ul style="list-style-type: none"> • <u>Checks vaccine reconstitution process is complete prior to distributing to immunisation stations with another nurse:</u> <ul style="list-style-type: none"> ○ All 10 vials are empty with blue drawing up needle in situ. ○ 10 syringes have safety needle + product label in situ. ○ Both nurses sign on the School Based Immunisation: Vaccine Management Nurse Daily Record Form (CHS516) that all 10 vaccines have been prepared correctly. 	<ul style="list-style-type: none"> • If there are any discrepancies or concerns that the process has not been followed, all immunisation activity must stop and the vaccine vials, syringes and consent forms reconciled in accordance with the principles of Speaking Up For Safety.
<p>5. Disposal of vials and drawing up needles</p> <ul style="list-style-type: none"> • Used vials and needles are disposed of in accordance with Waste Management and Sharps Management. 	
<p>6. Reconciliation of vaccines</p> <ul style="list-style-type: none"> • Drawing up nurse and team leader can reconcile vaccines at any time during the immunisation session and no less than: <ul style="list-style-type: none"> ○ Prior to leaving base ○ At the end of giving one type of vaccine (e.g. Nimenrix) or end of the scheduled session, the total number of reconstituted vaccines recorded and administered matches the number of consent forms and consents on Vaccinate WA. 	

Steps	Additional Information
<ul style="list-style-type: none"> ○ Refusals and wastage need to be considered. 	


Related internal policies, procedures and guidelines
<p>The following documents can be accessed in the CACH Clinical Nursing Manual: HealthPoint link or Internet link or for WACHS staff in the WACHS Policy link</p>
<p>Immunisation – Childhood</p>
<p>The following documents can be accessed in the CAHS Policy Manual</p>
<p>Waste Management</p>
<p>The following documents can be accessed in the CAHS Infection Prevention and Control Policies Manual</p>
<p>Sharps Management</p>
<p>The following documents can be accessed in the PCH Policy Manual</p>
<p>Labelling of Injectable Medications and Fluids</p>
<p>Medication Preparation, Checking and Administration</p>

Related internal resources and forms
<p>Administration of Vaccines by Registered Nurses</p>
<p>Australian Injectable Drugs Handbook</p>
<p>Community Health Medication Safety Toolbox</p>
<p>MIMS Online: Approved Product Information Database</p>
<p>PCH Pharmacy Intranet Page</p>
<p>Six Rights of Safe Medication Administration in Immunisation</p>
<p>Speaking Up For Safety</p>
<p>School Based Immunisation: Vaccine Management Nurse Daily Record Form (CHS516)</p>

Related external resources
<p>Australian Commission on Safety and Quality in Health Care’s Medication Safety Standard (Standard 4)</p>

National Centre for Immunisation Research and Surveillance Australia
National Hand Hygiene Initiative
National vaccine storage guidelines: Strive for 5
The Australian Immunisation Handbook
Western Australian Immunisation Schedule
5 Moments for Hand Hygiene

This document can be made available in alternative formats on request.

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Excellence
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