

Cold Chain Requirements in General Practice

-loving look after your vaccines

Jody Stephenson Clinical Nurse Consultant HNE PHU 10 March 2021 Phone 4924 6477 Email Hnelhd-phimmunisation@health.nsw.gov.au





- The 'cold chain' is the system of transporting and storing vaccines within the safe temperature range of +2°C to +8°C to ensure the vaccines remain potent and effective.
- COVID vaccines will be scares and precious we need to be able to manage our fridges and be able to report cold chain breaches.



Why is Vaccine Management Important?

- Vaccines are sensitive biological substances that can become less effective or even destroyed if they are frozen or exposed to temperatures outside the recommended range of 2°C to 8°C, and/or exposed to direct sunlight or UV or fluorescent light.
- The loss of vaccine effectiveness is cumulative and cannot be reversed.





- Storage
- Monitoring equipment
- Essential paperwork
- NSW Health Random Cold Chain Audit
- Cold Chain Breach Reporting



AstraZeneca storage highlights

- JN
- 2-8deg maximum 6 months as per expiry date
- Do not freeze
- Original packaging
- Once opened -max 6 hours at room temperature
- Total 48 hours fridge storage once opened
- Can be returned to fridge after being open and at room temp for < 6 hours
- Vaccine Operations Centre 1800 318 208
- SHEOC on 9859 5690







- Vaccines must be stored in a purpose built vaccines fridge
 - Fridge must be serviced every 12 months.
- All vaccines to be stored in original packaging (light sensitive)
- No vaccines to be stored on the bottom shelf need to be raised
- No vaccines to be touching the sides
- Do not crowd your fridge
- Recommended to use open weave baskets





- Data logger Must be
 - set for 5 minute recording intervals and set to run continuously
 - downloaded & saved on your computer every week and when a breach suspected. Advisable to have on shared drive that all staff can access in you absence
 - serviced/calibrated/checked for accuracy every 12 months.
 - battery changed as per manufacturers instruction or when the battery life displayed on either the data logger on the set up screen shows low or every 12 months



Checking battery on Logtag and TinyTag

Logtag – click on summary and check battery status. Anything other that OK needs replacing now







When you relaunch your data logger please ensure that you change your stop options from "when full" to "run indefinitely" This will prevent the data logger from stopping recording once full in case it is not downloaded one week.





- You <u>must have</u> a battery operated min/max thermometer for each vaccine fridge and each alternate cold storage. <u>This is in addition to the</u> <u>built in min/max thermometer on your fridge</u>
- Current, minimum and maximum temperatures must be recorded and plotted twice daily every day your practice is open
- Battery must be changed every 6-12 months
- Accuracy must be checked every 12 months



How to check accuracy of your thermometer

4.4 How to check the accuracy of a thermometer ('slush test')

- **1.** Fill a polystyrene or plastic cup with cold water.
- Place the cup in the refrigerator freezer until a fine layer of ice forms on the top and small sections of ice form within the fluid (this may take up to 2¹/₂ hours). The presence of ice is an indication that the temperature of the water has reached 0°C.
- **3.** Place the temperature probe into the middle of the container (be careful not to let the probe touch the container).
- 4. Observe the temperature on the display screen after 2 minutes.
- **5.** Document the date of the accuracy check.



Essential paper work



Stickers on your fridge, power point and meter box



DO NOT TURN OFF POWER BEFORE CONSULTING THE PERSON RESPONSIBLE FOR VACCINE MANAGEMENT



- Certificates of completion of NSW Health Vaccination and Cold Chain Management online training
- Vaccine management policies that are reviewed every 12 months
- Written procedures for what to do during a power failure
- Daily temperature graph
- ANNUAL STRIVE FOR 5 SELF AUDIT/ QARS



NSW Health requires GP facilities to use this temperature chart

You need to **plot and record** the minimum, maximum and current temperatures on this chart

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Vaccine storage troublesheet

Date	Time	Max/min. temperatures	Problem	Action taken	Results	Initials
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NSW health facilities Vaccine Refrigerator protocol

NSW HEALTH Vaccine Refrigerator Protocol

REFRIGERATOR MONITORING

CHECK refrigerator temperatures twice a day during operational hours and alm for 5° C

RECORD the minimum, maximum and current temperatures on the NSW Health vaccine refrigerator temperature chart

RESET the thermometer after recording temperatures

3

ACT if temperatures are outside of the recommended temperature range of +2°C to +8°C or the fridge has alarmed. Follow the cold chain breach protocol steps below.

COLD CHAIN BREACH STEPS

Take corrective ACTION where possible. Is the refrigerator door closed, refrigerator plugged in/turned on. Contact engineer if a refrigerator malfunction is suspected.

ISOLATE affected vaccines/medicines and label 'DO NOT USE'. Ensure vaccines can continue to be stored between +2°C to +8°C. Vaccines may need to be transferred to an alternative monitored refrigerator or cooler.

REPORT breach immediately to your manager/delegate Ph:

DOWNLOAD the data logger or review the back to base or automated temperature monitoring system and investigate potential cause and duration of breach.

NOTIFY the public health unit (1300 066 055) if temperature is <+2°C or > 48°C (excludes fluctuations up to +12°C s15 mins e.g. vaccine delivery). PHU will require cold chain breach reporting form, data logging and twice daily temperature readings to assess breach. DO NOT DISCARD vaccines until advice is received.

OTHER MEDICATIONS - Notify facility Pharmacy Service provider. Do NOT use medications until advice is received from Pharmacy.

DOCUMENT all activity on the back of the 'NSW Vaccine Refrigerator Temperature Chart - Fortnightly', i.e. thermostat adjustment, restocking, power outage, data logger removal etc. SUBMIT an IIMS/Ims+ for breaches resulting in vaccine wastage or patient recall and revaccination.

Order the *NSW Vaccine Refrigerator Temperature Chart - Fortnightly* from Toll Stream Direct. ORDER NUMBER: NH700227

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Remember me

NSW

CLINICAL

EXCELLENC

Vaccine Storage and Cold Chain Management

Summary

LOGIN

13.4 NSW Health Vaccine Refrigerator Temperature Chart

Order the NSW Health Vaccine Refrigerator Temperature Chart via the Stream Direct Catalogue as a POD print item (item number NH700227)

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In this collection Collection description Guidelines Posters Stickers Appendices

Collection description

This collection provides links to the full set of our National Vaccine Storage Guidelines 'Strive for 5' resources.

'Strive for 5' refers to 5 degrees Celsius (°C) — the point midway between +2°C and +8°C which is the temperature range recommended for vaccine storage. Many vaccines are damaged or destroyed at temperatures outside this range.

Reporting a cold chain breach- do not discard any vaccines until you speak to the PHU





For more information visit www.health.nsw.gov.au/manage-ccb

- Ensure surgeries at compliant with the requirements of Strive for 5 and NSW Cold Chain Toolkit for Immunisation Provider
- Conduct random cold chain audits on 50% of GP surgeries in HNE by December 2020



NSW Health resources

Home > Immunisation programs

Immunisation programs



- Immunisation Toolkit for GPs <u>NEW</u>
- NSW Immunisation Schedule 1 July 2020
- 2020 flu vaccine information for providers
- Vaccination advice during COVID-19
- Pharmacist vaccination



- More information
- Immunisation Toolkit for GPs NEW
- GP updates
- Public Health Units 1300 066 055
- Adverse events following immunisation
- Vaccine ordering link
- Cold chain management
- Cold chain learning module (with certificate of completion)

Cold Chain Toolkit for Immunisation Providers

August 2020

NSW Health



Take home to do list – rotate your stock



- Ensure you have battery operated min/max thermometers
 - Batteries changed every 6-12 months
- Ensure your fridge is serviced every 12 months
- Ensure your data logger is set for 5 minute recording, battery is replaced and serviced as per manufacture instructions or every 12 months and is set to run continuously
- Ensure no vaccines a stored on the floor of your fridge and always in their original packaging
- Ensure you and another staff know how to down load your data logger AND attach this file to an email
- COMPLETE YOUR ANNUAL STRIVE FOR 5 SELF AUDIT or QARS
- Consider purchasing extra PBVF now if you need additional

Hunter New England Local Health District

Additional resources

- NSW cold chain toolkit for Immunisation Providers
- Strive for 5
- Temperature Graph
- <u>https://www.health.gov.au/resources/publications/national-vaccine-</u> <u>storage-guidelines-strive-for-5-vaccine-fridge-temperature-chart-poster</u>
- Safe Vaccine Storage Checklist
- <u>https://www.health.nsw.gov.au/immunisation/Documents/safe-vaccine-storage-checklist.pdf</u>
- Better Health Centre: Email. nslhd-bhc@health.nsw.gov.au Fax. 02 9887 5452

NSW Health Online Cold Chain Learning Module - <u>https://nswhealth.seertechsolutions.com.au/public_c</u>ontent/HETICP/HETI/CCMWebv3/story_html5.html







NSW Health works in partnership with schools to offer vaccines recommended for adolescents by the National Health and Medical Research Council (NHMRC) in a school-based vaccination program

Parent information kits are sent home to parents early in the school year.

To consent to vaccination, parents are advised to read all the information provided, complete and sign the consent form for whichever vaccines they wish their student to receive, and return it to their child's school.



Parent information kit Year 7







Parent Information



PARENT INFORMATION SHEET

NSW School Vaccination Program

NSW Health works with schools to offer human papillomavirus (HPV) and diphtheria-tetanuspertussis (dTpa) vaccines to Year 7 students in a school-based vaccination program. These vaccines are recommended by the National Health & Medical Research Council (NHMRC) and funded under the National Immunisation Program.

- · Information about the vaccines and the diseases they protect against are included in this Parent Information Sheet
- . For your child to be vaccinated, consent for each vaccine must be provided by the parent /guardian on the enclosed Consent Form. The vaccines are only provided free at school if you complete, sign and return the Consent Form while your child is in Year 7.
- . Consent can be withdrawn at any time by following the advice on page 2.
- . If you do NOT wish your child to be vaccinated against a disease, do NOT sign your name next to that vaccine
- · A Privacy Statement that explains how the information you provide is collected and used is also included on page 4.

For more information, please contact your local public health unit on 1300 066 055 or visit www.health.nsw.gov.au/immunisation.



Frequently asked questions

Q. How do vaccines work?

Vaccines work by triggering the immune system to fight certain infections. If a vaccinated person comes into contact with these infections, their immune system is able to respond more effectively. preventing the disease developing or greatly reducing its severity.

Q. How safe are vaccines?

Vaccines used in Australia are safe and must pass strict safety testing before being approved by the Therapeutic Goods Administration (TGA). In addition, the TGA monitors the safety of vaccines once they are in use.

Q. What are the side effects of vaccination?

Side effects are commonly mild and usually involve pain, swelling and redness at the injection site. Serious side effects are extremel rare. NSW parents who were followed up in the days after HPV vaccination reported that 9% of students experienced mild side effects while only 0.4% required medical attention. More information about side effects is available in the Consumer Medical Information (CMI) for the vaccine available from www.health.nsw.gov.au/ schoolvaccination.

Parents concerned about side effects after vaccination should contact their GP who should also make a report to the local public health unit.

Q. What is anaphylaxis?

Anaphylaxis is a severe allergic reaction that may result in unconsciousness and death if not treated quickly. It occurs very rarely after any vaccination. The school immunisation nurses are fully trained in the treatment of anaphylaxis. Any history of anaphylaxis may mean that a student should not receive a certain vaccine

Q. What if my child has asthma and takes cortisone or prednisone by a "puffer"? The vaccines can be safely administered to someone who has

asthma regardless of which medications they are taking. Q. Should the vaccine be given

to a female student who is or thinks she may be pregnant?

No. Any female student who is, or thinks she may be, pregnant should not be vaccinated. On the day of the clinic the vaccination nurse will ask female students if they are or could be pregnant. If a student answers yes to this question, she will not be vaccinated. The student will be urged to immediately discuss the issue with her parent/guardian and to seek medical help. She will also be provided with contact details for a health referral service that will provide advice, support and guidance.

Q. Can I withdraw consent?

Consent can be withdrawn at any time by providing the school with written notification of the withdrawal of consent or telephoning the school to withdraw consent.

2 NSW HEALTH - YEAR 7 VACCINATIONS - PARENT INFORMATION SHEET

Information about each of the vaccines

Q. What if I prefer to wait		Human Papillomavirus (HPV)	Diphtheria-Tetanus-Pertussis (dTpa)
until my child is older? These vaccines can only be provided at school by you returning the original consent form while your child is in Year 7. If you choose to wait until your child is only you will need to make arrangements with your CP and there may be cost in wheved. O. Will I receive a record of the vaccinations? A record of vaccination will be given as a physical card or a test message sent to the mobile phone number you provide on the Consent Form You should not assume that your child has been vaccinated if you do not receive a record of vaccination. Advice your GP that the vaccination has been given the next time you visit. G. What If my child missed out	What is the disease and how is it spread?	Name academonese (IPP) is a common visu allicity baltimes and women. IPP's as parted travaly partial contract any gas with interesties who has the statu. The virus passes through tiny bands in the skin and and ganad Through balds or done took phila. Conclume of let minited protection, as they do not cover all of the gantal skin. Not assubly at these packed with see particular live infection at some time in their have. While the body subly clears the infection study and there aren a synchronic. This canonomies cause series all ness, including - almost all causes of carvical across - 60% of rupping rupping a carees - 60% of rupping rupping a carees - 60% of carbiparping across - 60% of participarping across - 60% of part	Debetwei is a contagos and potentiali Nie theratemis bactmai indicision that causes were herateling officials, hard takan and new damoge. People can get diptitivel by beaching in the bactmai and an indicate granchina coupled or seenced, in hom does cratical with dickarges. Hom an infected percosi's mouth, rose thand or sins. Tetasas is a seven, cellen if ad daeses of the nervices system. The percon affers seven particit made grants, convision and bolgos. Clem with modern inferior care about 1 in Dispectivel and bolgos. Den with modern inferior care about 1 in Dispectively and bolgos. Den with modern inferior care about 1 in Dispectively and that as a cased by datatin faced in soil and inferioration are care to the site full and contained with soil. Add one memory is the site full are cardinarized with loss data or memory an anxing rough careful is a highly released and bacteria films care and the careful and datasets and addisances that and datasets an anxing rough rough is a highly released and careful and careful releases. The careful is a highly released and careful and an anxing rough rough is a highly released and careful and and release. About 1 rough is a highly released and rough rough careful and and release. About 1 rough is a highly released and rough results and and release. About 1 rough is a highly released and rough releases and and release. About 1 rough is a highly released and rough releases and and release. About 1 rough rough releases and and release. About 1 rough rough releases and and releases about 1 rough rough releases and and releases. About 1 rough
on the vaccine at school? Every effort will be made to vaccinate your child at subsequent school clinics during the Year 7 school year. Where this is not possible, you will be advised of arrangements for catch-up		Vecceding makes will prevent cancers and genital warts and will also help to protect females from cervical cancer.	catch whooping cough from an infected person die from prevunna or brain demage. Whooping cough is spread to other people by depiels from coughing or spread in the spread service who whooping cough can spread it to other people for up to 3 weeks after the oract of cough.
vaccination. O. What will happen to my child's information? The information you provide on the Consent Form is subject to strict confidentially and privacy protections contained in NSW and Commonwealth legislation (see the enclosed Privacy Statement). The information will be entered into a NSW Health immunisation register and then uploaded to the Australian Nmunisation Register (AIRs oit can be fined to your childy existing immunisation history	Which vaccine will be used?	An IEV exame that protects against 9 types of IEVP 66, 10, 88, 81, 33, 65, 53 and 550 will be offending in 2-does care at least 16 months apart. The later is themational evidence molations that most "their 7 students who received 2 does of any IEV vaccine all best 6 months agart are bully vacantelia and do not need a their doals. "Duberts with students" more systems are all monomous balls and do not need a their doals. "Duberts with students" more and their as the BU monomous balls and a student of IVV accine at their BU monomous balls and a student of IVV accine at their BU monomous balls and a student of IVV accine at their BU monomous and their and T symphotic encounted for particular documents of the student of T symphotic encounted for particular documents and their particular and their BU monomous presents and T symphotic encounted for particular documents and particular and their BU and their particular and their part	A contribution eightness lettawas whopeing cough waters elifelia will be offered as an elifectation against deptithensi, latanua and whopeing cough. This booster frame is exponsible for mail-barrow endocoping cough, wateries given in childhood deptithensi elifanata-elifocoping cough wateries given in childhood. (2017) should reveal the d'Baa vaccine to also protect them against whopping cough.
and viewed on MyGov. Female students receiving HPV vaccine – by signing the Consent form, you are agreeing to disclose your childs theath information for linkage to the National Cervical Screening Program Register in the future. Q. Where can I find more	Who should be vaccinated?	Al students in Year 7 should nexine 2-dose of HPV vaccine (those with significantly impained immune spatients should analyze those 3 dose of the vaccine at the 40 ⁻² new above. Regular cervical screening (periodary called Pap smean) is still impartant for vaccined should an year of the Vaccine des not protect against all types of HPV that can cause cervical cancer. All women from 35 years of age who have ever been asculty active should have a Carcinal Screening Test every Systam, regardless of their HPV vaccination status.	All students in Year 7 should receive Toposter dose of oliga vascine.
information about immunisation? More information is available:	Who should	HPV vaccine should not be given to people who:	d'ipe vaccine should not be given to people who
More information is available: by contacting your local public health unit on 1300 066 055 or visiting the NSW Health website at www.health.rsw.gov.au/immunisation on the National Center for Immunisation Research and	not be vaccinated?	Per Faculte association to grant any president model ender may be pregnant ense that antiphysissis following a previous dose of vaccine ense a factory of averafysiosis to predit have had anaphysissis following any of the vaccine additives (see below)	the had anaphylasis following a previous dose of vaccine two had anaphylasis following any of the vaccine components (see below)
on the Production Center of Immunitation Research and Surveillance website in a <u>www.rick.comg.au</u> in the Australian Immunisation Handbook at <u>www.immunise.health.gov.au</u> on the Therapeutic Goods Administration's (TGA) website at	What additives does the vaccine contain?	The vectorie confaint yees, aluminium adjuvant, sodium chloride; L-hiddane, polysorbate and sodium borate. These additives are included in very small amounts to either assist the vectorie to work or to act as a pretervalve.	The vaccine contains aluminium hydroxide and phosphete, traces of formal dehyde, polysorbate 80 and glycline and was exposed to bovine-derived materials during manufacture.
www.bagooxau - Australiain immunication Register (AIR) website at www.bumanservices.gov.au/individuals/services/medicane/ australian-immunication-register	How effective is the vaccine?	The sacross exolution against high value PV prest that cause over 90% downsid a cause in concern and alth prestigation additional PPV highest that cause cancers in men. The vaccine provides bed protection when gives in a grouper against when it is given to conneces before the type became exolution cause. The sacross end of the sacross and the became exolution cause and the transmission of the sacross and protection once than to years all for lease gives. As convid cancer sample access and inclu be evident for same gives. As convid cancer cause cancers will not be reader to prove time. However, there has been a "7% includions in HV gives and provide to man 2% of convid a cancer.	The sectors is my effective representing distillence and latence and about BOX effective representing whosping coupt.

NSW HEALTH - YEAR 7 VACCINATIONS - PARENT INFORMATION SHEET



Year 7 consent form

Population

Health





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Parent information kit Year 10







Parent Information



MENINGOCOCCAL ACWY VACCINATION Parent Information Sheet

NSW Health is offering vaccination against four types of meningococcal disease (given as one injection) through the school vaccination program. Signed parental/guardian consent must be provided.

Your next steps

- · Carefully read this information sheet.
- If you would like your child to be vaccinated against meningococcal ACWY disease, complete the Consent Form where you see this symbol 🏝 and give the signed Consent Form to your child to return to school.
- · If you do NOT wish your child to be vaccinated against meningococcal ACWY disease, do NOT complete or return the Consent Form

Q. What is meningococcal disease?

Meningococcal disease is a rare but serious infection that usually leads to meningitis (inflammation of the lining of the brain and spinal cord) and/or septicaemia (blood poisoning). Symptoms of meningococcal disease may be non-specific but may include sudden onset of fever, headache, neck stiffness, joint pain, a rash of red-purple spots or bruises, dislike of bright lights, nausea and vomiting. Up to 10 per cent of meningococcal infections are fatal even with appropriate antibiotic treatment, and survivors may be left with long-term complications.

Q. How is meningococcal disease spread?

Meningococcal bacteria are passed between people in the saliva from the back of the nose and throat. This generally requires close and prolonged contact with a person carrying the bacteria who is usually completely well. An example of 'close and prolonged contact' is living in the same household or intimate (deep) kissing. Meningococcal bacteria are not easily spread from person to person and the bacteria do not survive well outside the human body.

Q. How do vaccines work?

Vaccines work by triggering the immune system to fight certain infections. If a vaccinated person comes into contact with these infections, their immune system is able to respond more effectively, preventing the disease developing or greatly reducing its severity.

Q. How effective is the meningococcal ACWY vaccine?

A single dose of meningococcal ACWY conjugate vaccine is very effective in providing protection against these four types of meningococcal disease. The vaccine does not protect against meningococcal disease caused by type B.

Q. Who should be vaccinated in this program?

All students in Year 10 in secondary schools, and those aged 15-19 years attending Intensive English Centres, should be vaccinated to be protected against meningococcal serogroups A. C. W and Y.

Q. Who should not be vaccinated?

Meningococcal ACWY vaccine should not be given to people who have had anaphylaxis:

· following a previous dose of meningococcal vaccine · following any of the vaccine additives

People with a known hypersensitivity to diphtheria toxoid should also not be vaccinated with meningococcal ACWY vaccine.

Q. What is anaphylaxis?

Anaphylaxis is a severe allergic reaction that may result in unconsciousness and death if not treated quickly.

It occurs very rarely after any vaccination. The school immunisation nurses are fully trained in the treatment of anaphylaxis.

Q. Hasn't my child already received the meningococcal ACWY vaccine?

The Meningococcal ACWY vaccine has been included on the National Immunisation Program for children aged 12 months of age since July 2018. Your child may have previously received a meningococcal C vaccine which only protects against meningococcal C disease.

A small number of students with certain medical conditions (such as no spleen or immune deficiency) may have previously been given this vaccine. If so, please discuss with your GP or specialist if your child is due for a booster.

MENINGOCOCCAL ACWY VACCINATION - PARENT INFORMATION SHEET

Q. My child has already received a meningococcal C vaccine - is it safe to receive meningococcal ACWY vaccine?

Most children will have received meningococcal C vaccine as infants. In some countries an adolescent booster is recommended, and this ACWY vaccine will provide a booster dose against meningococcal C disease as well as protect against types A, W and Y. Some children will have received a dose of meningococcal C vaccine in 2015-2018 as part of the catch-up for No Jab, No Pay. Having a dose of meningococcal ACWY vaccine now is safe. It is preferable to leave at least 4 weeks between doses for optimal protection against all types.

Q. What are the other indications for this vaccine?

This vaccine is also recommended for people planning travel involving a greater risk of exposure to meningococcal disease, including the Hajj. The vaccine is also recommended for certain occupations, such as microbiology laboratory staff, and for people with certain medical conditions, such as not having a spleen.

Q. What additives does the meningococcal ACWY vaccine contain?

The vaccine may contain trometamol, sucrose and sodium chloride. Additives are included in very small amounts to either assist the vaccine to work or to act as a preservative.

Q. How safe are vaccines?

Vaccines used in Australia are safe and must pass strict safety testing before being approved by the Therapeutic Goods Administration (TGA). In addition, the TGA monitors the safety of vaccines once they are in use.

Q. What are the side effects of meningococcal ACWY vaccination?

Side effects are commonly mild and usually involve fever, headache, dizziness or pain, swelling and redness at the injection site. Injection site reactions generally resolve within 2-3 days. Serious side effects are extremely rare. More information about side effects is available in the Consumer Medical Information (CMI) for the vaccine available from www.health.nsw.gov.au/ schoolvaccination.

Parents concerned about side effects after vaccination should contact their GP who should also make a report to the local public health unit.

Q. Should the vaccine be given to a female student who is or thinks she may be pregnant?

No. Any female student who is, or thinks she may be, pregnant should not be vaccinated. On the day of the clinic the vaccination nurse will ask female students if they are or could be pregnant. If a student answers yes to this question, she will not be vaccinated. The student will be urged to immediately discuss the issue with her parent/guardian and to seek medical help.



She will also be provided with contact details for a health referral service that will provide advice, support and guidance.

Q. What if my child has asthma and takes cortisone or prednisone by a "puffer"?

Meningococcal ACWY vaccine can be safely administered to someone who has asthma regardless of which medications they are taking.

Q. Who can consent to vaccination and can consent be withdrawn?

Only parents/guardians can consent to vaccination for students less than 18 years of age. Students aged 18 years and over may consent to their own vaccination and should complete and sign the Consent Form where 'Parent/Guardian' is indicated. Consent can be withdrawn at any time by providing the school with written notification of the withdrawal of consent or telephoning the school to withdraw consent.

Q. What do I do if my child missed out on the vaccine because of illness or absence on the day of the nurses' visit?

Every effort will be made to vaccinate your child during the school year. Where this is not possible, you will be advised of arrangements for catch-up vaccination.

Q. Will I receive a record of the vaccination?

A record of vaccination will be given as a physical card or a text message sent to the mobile phone number you provide on the Consent Form. You should not assume that your child has been vaccinated if you do not receive a record of vaccination. Advise your GP that the vaccination has been given the next time you visit.

Q. What will happen to my child's information?

The information you provide on the Consent Form is subject to strict confidentiality and privacy protections contained in NSW and Commonwealth legislation (see the enclosed Privacy Statement). The information will be entered into a NSW Health immunisation register and then uploaded to the Australian Immunisation Register (AIR) so it can be linked to your child's existing immunisation history and viewed on MyGov.

Q. Where can I find more information about immunisation?

More information is available:

- by contacting your local public health unit on 1300 066 055 or visiting the NSW Health website at www.health.nsw.gov.au/meningococcalW
- on the National Centre for Immunisation Research and Surveillance website at www.ncirs.org.au
- in the Australian Immunisation Handbook at www.immunise.health.gov.au
- on the Therapeutic Goods Administration's (TGA) website at www.tga.gov.au
- · Australian Immunisation Register (AIR) website at www.humanservices.gov.au/individuals/services/ medicare/australian-immunisation-register

6



Year 10 consent form

	Consent for Meningococcal ACW Vaccination	Y 🗰				
	Parent/Guardian to complete. Please print in CAPITAL le Zo 1. Student's Details Surnamo	etters using a black or blue pen.				
	Given Nama/s					
	Date of Birth Gender ////MF Name of School	Grade				
	Medicare Number	Number beside your childs name on the Medicare card				
	1 2. Indigenous Status No Yes, Aborghe Yes, Torres Stret Nander Yes, bo 3. Your Details - Parent or Legal Guardian	oth Aboriginal and Torres Strattislander				
	I have need and understood the information I declare, to the provided negating the benefits and the possible side effects of the Meningococcal ACWY vectors. Thereby give convert for my child, named above. 2. Does not h	w/e an anephyla				
	Vaccine. Parent Int Name of Paront/Guardian lag Jour series		Vaccination	MNW2101000001	Parent/Guardian Meningococo	
	Horne Address (e.g. 5 SMITH LANE)	Ra Parent/Guard Namo of Studer	an to complete If (e.g. JANE SMITH)		Meningococcal ACWY Record o A Parent/Guardian to complete Namo of Student (e.g. JANE SMITH)	fVaccination
	Suburb Mobile Number Best Atem	Postcode rate Number (n OFFICE USE 0	500 X		OFFICE USE ONLY	
	Signature of Parent/Guardian Dete		Time of Vaccination (24h) Vaccine B	Batch Number	Arm Left Time of Vaccination (24h) Vacc	ne Betch Number
	x	Nurse's Signetur	•	Daxe	Right : Nurse's Signature	Date
		× Nurse's note			×	· · · · · · · · · · · · · · · · · · ·
		Reason not ve				
		Addents Related Univel No signatu Consent w Other			 Reap this record, as you may be required to provide this information size. 	What to do if a reaction occurs - Dut a certification to injustion sto to rease and drings - Take paraceterol for pain. - Drink exter Tuda.
					If your child suffers a reaction that you are co	
					1787a	
					NSW	
Health Population Health						

2021 Program Schedule



Year	Disease	Vaccine	No. of doses	Gap
7	HPV – Human Papillomavirus	Gardasil 9	2	6 months
	Diphtheria/Tetanus/ Pertussis	Boostrix	1	
10	Meningococcal ACWY	Nimenrix	1	

Catch up

Catch-up vaccinations are offered within the school program in Year 8 & Year 11 when:

Year 8 – ONLY if the consent form was signed and returned to school in Year 7 **Year 11** – ONLY if the consent form was signed and returned to school in Year 10



Record of Vaccination card

Parent/Guardian Record of	Vaccination
Name of Student	
Vaccine Dose Arm Vaccine Batch Number	Time of Vaccination (24hr) Nurse's Signature
dTpa	
Dose Date (DD/MM/YY)	December 2018

Why you have been given this card

- This record has been provided so that you know which vaccine/s have been given to your child at school.
- The vaccination details will be uploaded to the Australian Immunisation Register (AIR) to provide a complete immunisation history for your child.
- You should advise your GP of the date of this vaccination so that your child's records are kept up to date.

What to do if a reaction occurs

- Put a cold damp cloth on the injection site to relieve tenderness.
- · Take paracetamol for the pain.
- Drink extra fluids.
- Please contact your local GP if your child suffers a reaction that you are concerned about.







SV Program in Hunter New England

• Schools → 145

Students
 Year 7 = 12,142
 Year 10 = 10,952

• Teams _____ 25

• Nurses — 196



THANK YOU!













This order also authorises the Authorised Persons who has completed additional training referred to at clause 2(2) and clause 2(3), respectively, to supply:

Poison or restricted substance					
Tuberculin (purified protein derivative)	Tuberculosis (BCG) vaccine				
SARS-COV-2 (COVID-19) vaccine					





2021 Influenza Vaccine presentation and free vaccine eligibility



Vaxigrip Tetra® and Fluarix® Tetra

Registered for use in people aged 6 months and over:

- For universal 6 months to less than 5 years influenza vaccination program
- Give two doses one month apart for children aged 6 months to less than 5 years if first year of receiving flu vaccine
- Available in 10 and single packs
- Children should receive a full dose (i.e. not a half dose)
- NIP vaccines do NOT contain latex













5 YEARS TO 64 YEARS

Vaxigrip Tetra®, Fluarix® Tetra and Afluria® Quad

- People 5 years and over with medical risk factors predisposing to severe influenza
- All Aboriginal persons 5 years to 64 years of age
- Pregnant women
- Give two doses one month apart for children aged 5 years to less than 9 years if first year of receiving flu vaccine
- Vaxigrip Tetra and Fluarix Tetra are available in 10 and single packs. Afluria Quad is only available in a 10 pack
- Children should receive a full dose (i.e. not a half dose)
- NIP vaccines do NOT contain latex
- Do not use Afluria Quad for children less than 5 years of age





Add



65 YEARS AND OVER

Fluad® Quad

- Adjuvanted quadrivalent vaccine
- All persons aged 65 years and over
- Milky-white suspension
- Available in 10 packs
- NIP vaccines do NOT contain latex
- Do not use in pregnant women or children



Ten pack dimensions: 15.4 cm (L) x 13 cm (H) x 2.3 cm (W)





Australian Government

Department of Health

AUSTRALIAN TECHNICAL ADVISORY GROUP ON IMMUNISATION (ATAGI) CLINICAL ADVICE

Issue date: March 2021

Table 1. Seasonal influenza vaccines registered and available for use in Australia in 2021, by age

Vaccine Registered age group	Vaxigrip Tetra 0.5 mL (Sanofi)	Fluarix Tetra 0.5 mL (GSK)	FluQuadri 0.5 mL (Sanofi)	Influvac Tetra 0.50 mL (Mylan)	Afluria Quad 0.5 mL (Seqirus)	Flucelvax Quad 0.5 mL (Seqirus)	Fluad Quad 0.5 mL (Seqirus)
6 to 35 months (<3 years)	\checkmark	\checkmark	\checkmark	X	X	X	X
\geq 3 to <5 years	\checkmark	\checkmark	~	\checkmark	X	X	X
≥5 to <9 years	√*	√*	\checkmark	\checkmark	√*	X	X
\geq 9 to <65 years	√*	√*	√	\checkmark	√*	\checkmark	X
≥65 years	\checkmark	\checkmark	~	\checkmark	\checkmark	\checkmark	✓

Ticks indicate age at which a vaccine is registered and available. Shaded boxes indicate the vaccine is funded under the NIP for eligible people. * NIP funding only for Aboriginal and Torres Strait Islander people, pregnant women and people who have certain medical conditions.




- The preferred minimum interval between influenza vaccine and a dose of COVID-19 vaccine is 14 days.
- Influenza vaccine can be given before or after any dose of a COVID-19 vaccine, with a minimum interval of 14 days.
- When scheduling influenza and COVID-19 vaccines, consider the following principles:
- People in phase 1a for COVID-19 vaccination should receive the COVID-19 vaccine as soon as it is available to them, and then receive their influenza vaccine.
- People in later phases for COVID-19 vaccination should receive their influenza vaccine as soon as it is available, and then receive their COVID-19 vaccine when it becomes available to them.



Always Was, Always Will Be







NSW Immunisation Schedule

Funded July 2020



						GOVERNMENT	
			CHILDHO	DOD VAC	CINES		
AGE		DISEASE		VACCI		INFORMATION	
Birth	Hepatitis B					Within 7 days of birth (ideally within 24 hours)	
6 weeks	Diphtheria, tetanus, pertussis, Haemophilus influenzae type b, hepatitis B, polio					ROTARIX: Dose 1 limited to 6-14 weeks of age BEXSERO: Prophylactic paracetamol recommended. Catch up available for	
	Pneumococcal			PICEVER/ARTID (IPI)			
	Rotavirus			ROTARI		 Aboriginal children <2 until 30/06/2023 	
	Meningococcal B (Aboriginal [†] children only)			BEXSER			
4 months	Diphtheria, tetanus, pertussis, Haemophilu influenzae type b, hepatitis B, polio					ROTARIX: Dose 2 limited to 10-24 weeks BEXSERO: Prophylactic paracetamol	
	Pneumococcal					recommended. Catch up available for	
	Rotavirus			RUTARIX (Ural)		Aboriginal children <2 until 30/06/2023	
5 months	Meningococcal B (Aboriginal Diphtheria, tetanus, pertussis influenzae type b, hepatitis B,		Haemophilus	BEXSERO (IM) INFANRIX HEXA (IM)		Children 26 months with at risk conditions for IPDI are recommended to receive an additional dose of PREVENAR 13 - see AIH* Aboriginal children 26 months with certain at risk conditions may require an additional	
						dose of Bexsero – see AIH*	
2 months	Meningocoo	ccal ACWY		NIMENF	(MD XB		
	Pneumococ				AR 13 (IM)	Bexsero: Prophylactic paracetamol	
	Measles, mumps, rubella			MMR II (DR PRIORIX	recommended. Catch up available for Aboriginal children <2 until 30/06/2023	
	Meningococcal B (Aboriginal children only)			(IM or S		Aborginal children <2 until 30/06/2023	
0 months			children only)	BEXSER			
8 months	Diphtheria,	tetanus, pertussis		INFANR			
	Manadana	and a deallar seed		TRIPAC		-	
	Measles, mumps, rubella, varicella				AD (IM or SC)		
	Haemophilus influenzae type b		b		3 (IM OR SC)	-	
4 years				INFANRIX-IPV OR QUADRACEL (IM)		Children with at risk conditions for IPD [‡] are recommended to receive an additional dose of PNEUMOVAX 23 - see AIH*	
		AT RIS	K GROUPS, AD	OOLESCE	INTS AND A		
AGE/GRO	UP	DIS	EASE	VACC	NE	INFORMATION	
All people with asplenia, hyposplenia, complement deficiency and treatment with eculizumab		Meningococcal ACWY		NIMENRIX (IM) BEXSERO (IM)		See AIH* for required doses and timing Additional groups are recommended	
		Meningococcal B				to receive these vaccines but these are not funded	
>5 years wit or hyposple		Haemophilus influenzae type b		ACT-HIB (IM or SC)		If incompletely vaccinated or not vaccinated in childhood	
Year 7		Diphtheria, teta			RIX (IM)		
		Human papillomavirus			SIL 9 (IM)		
/ear 10			Meningococcal ACWY		RIX (IM)		
Pregnant		Influenza		INFLUE		Influenza: Any trimester	
		Pertussis		BOOSTRIX OR ADACEL (IM)		20-32 weeks	
Aboriginal people ≥50 years		Pneumococcal			NAR 13 (IM) the IOVAX 23 (IM)	en Prevenar 13: ≥50 years Pneumovax 23: 2-12 months later Pneumovax 23: at least 5 years later	
70 years		Pneumococcal		PREVE	NAR 13 (IM)	Pneumococcal funded for people ≥70	
		Zoster		ZOSTAVAX (SC)		Zoster: Catch up available for 71-79 year olds until 31/10/2021	
People with conditions f		See the online AIH* for conditions recommended to receive PREVENAR 13 and PNEUMOVAX				e PREVENAR 13 and PNEUMOVAX 23	
				LUENZA			
AGE/AT R	ISK CONDI	TION	RECOMMEND	DATION	INFORMAT	TION	
	6 months <5 y						
Aboriginal people 2 6 months People with at risk conditions 26 months 265 years					ands and eligibility see: sw.gov.au/immunisation/Pages/flu.aspx		
Pregnant wo	omen						



13

Invasive pneumococcal disease notifications by age and Indigenous status, Australia, 2006-2015



- 3x higher in <5yrs
- 10x higher in 5-49yrs
- 6x higher in ≥50yrs



New chart



Figure 1. NIP funded pneumococcal vaccine schedule from 1 July 2020

The list of risk conditions is set out in **Table 1** over the page. Some of these conditions are eligible for NIP funded doses of pneumococcal vaccine.



Pneumococcal vaccination for people with risk conditions for pneumococcal disease



Anyone over 12 months of age who is diagnosed with a risk condition should receive:



- diabetes
- smoking
- harmful use of alcohol



See the Australian Immunisation Handbook for the full list of risk conditions, including which conditions are funded under the National Immunisation Program.



- Bexsero is on the routine childhood schedule for Aboriginal children at 6 weeks, 4 months and 12 months
- Catch up funded for children <2 years of age until 30 June 2023, number of doses required is age specific,
- Paracetamol is recommended for children less than
 2 years of age prior to and post vaccination
- Not included in "up to date" calculations for purposes of payments i.e. "No Jab, No Pay"



Men B Increased risk





Meningococcal disease notification rates (all ages) by serogroup & Indigenous status, Australia, 2006-2015



• Men ACWY gap 5-14yrs



Additional doses



Meningococcal B vaccine for Aboriginal and Torres Strait Islander children

No changes to handbook recommendations, but new NIP funding for MenB vaccine:

- Meningococcal B vaccine (Bexsero®) will be NIP funded for Aboriginal and Torres Strait Islander infants.
 - · 2, 4 and 12 months of age with no medical risk conditions (3 doses)
 - 2, 4, 6 and 12 months of age with risk conditions for IMD (4 doses)

List 1. Risk conditions for invasive meningococcal disease that are eligible for both MenACWY and MenB NIPfunded* vaccines

- Defects in, or deficiency of, complement components, including factor H, factor D or properdin deficiency
- Current or future treatment with eculizumab (a monoclonal antibody directed against complement component C5)
- Functional or anatomical asplenia, including sickle cell disease or other haemoglobinopathies, and congenital or acquired asplenia

* Please refer to The Australian Immunisation Handbook available at immunisationhandbook.health.gov.au for advice on persons who are strongly recommended to receive meningococcal vaccination but not eligible for NIP funded MenB and MenACWY vaccines





Prophylactic Paracetamol After Meningococcal B Vaccination Reduces Postvaccination Fever and Septic Screens in Hospitalized Preterm Infants

Magali Dubus ¹, Shamez Ladhani ², Vimal Vasu ¹ Affiliations + expand PMID: 31815841 DOI: 10.1097/INF.00000000002507

Abstract

Background: Following the introduction of the 4CMenB (Bexsero, GlaxoSmithKline, Rixensart, Belgium) vaccine against Meningococcal B into the UK vaccination schedule, Public Health England advised paracetamol to be given prophylactically with the vaccine. This was based on observations of increased postvaccination febrile reactions in term infants. Evidence in preterm infants was lacking. We aimed to evaluate whether (i) 4CmenB is associated with an increase in adverse events (AEs) in the 48 hours after vaccination in preterm infants and (ii) the impact of prophylactic paracetamol on AEs.

Conclusions: 4CMenB is associated with AEs in hospitalized preterm infants. Prophylactic paracetamol administration attenuates this.





 People with the following at risk conditions are now funded to receive Meningococcal B (Bexsero) vaccine

- Asplenia / Hyposplenia
- Complement deficiency
- Treatment with Eculizumab







https://mmunisationhandbook health gov au/resources/publications



Vaccination for travel





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Protecting and improving the nation's health



PHE monitoring of the early impact and effectiveness of COVID-19 vaccination in England

22 February 2021

Figure 2a: Trends in weekly rate of hospitalisations for COVID by age group December 2020- February 2021 (source - SARI-Watch)



COVID-19 vaccination rollout in remote Indigenous communities may fail unless more consultation is sought, experts say



"It's just that it's new and I guess they need some more time to be reassured that it's safe and of benefit."

Aunty B said she was "very willing" to receive the COVID-19 vaccination, however many Indigenous people were fearful about having no choice in the matter.

"One of the issues for generations of Aboriginal people is being forced to do things that they haven't clearly understood what is happening and the consequences of those actions being taken," she said.

A 'fear' of the unknown

Charles Darwin University Larrakia academic-in-residence and elder Aunty Bilawara Lee is an expert in cross-cultural communication.



COVID-19 vaccination rollout in remote Indigenous communities mayfail unless more consultation is sought, experts say (msn.com)26





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Coronavirus (COVID-19) Updates and Information

Coronavirus (COVID-19) is an evolving global health concern. This page will be updated with the latest information as it becomes available.

For up-to-the-minute targeted information for Aboriginal and Torres Strait Islander peoples, visit the <u>Australian Federal Government Department</u> of Health (DoH) website.

For latest news and information on the COVID-19 vaccines click here.

Important COVID-19 resources and updates:

<u>COVID-19 Vaccines common questions</u>



COVID-19 Updates and Information (naccho.org.au)





A practical guide for improving vaccine communication and fighting misinformation





The COVID-19 Vaccine Communication Handbook.pdf

Long Covid



Long Covid symptoms

Percentage of patients with symptoms



Source: Agostino Gemelli University



However, such studies focus only on the minority of people who end up needing hospital treatment.

The <u>Covid Symptom Tracker App</u> - used by around four million people in the UK - found 12% of people still had symptoms after 30 days. Its latest, unpublished data, suggests as many as one in 50 (2%) of all people infected have long-Covid symptoms after 90 days.



https://www.bbc.com/news/health-54296223

Coronaviruses





- Hundreds of corona viruses animals
- Jump to humans spillover
- 7 corona viruses cause human disease
- 4 mild disease 229E, OC43, NL63 and HKU1
- SARS (severe acute respiratory syndrome)
- MERS (Middle East respiratory syndrome
- SARS-CoV-2 causes Covid-19



Australia's COVID-19 vaccination schedule

Vaccination roll-out by group and estimated population covered.

Phase 1A

1.4 million doses

- Quarantine and border workers
- frontline health care workers
- aged care and disability care staff and residents.

Phase 1B

14.8 million doses

- Indigenous people aged 55 and over
- non-Indigenous people aged 70 and over
- all other health care workers
- younger adults with underlying medical conditions or disabilities
- critical and high risk defence, police, fire, emergency services and meat processing workers.

Phase 2A

15.8 million doses

- Indigenous people aged between 18 and 54
- non-Indigenous people aged 50 and over
- other critical and high risk workers.

Phase 2B

16 million doses

- · Balance of population aged 16 and over
- follow-up of any adults missed in previous phases.

Phase 3 13.6 million doses

Children under 16 (if recommended, Pfizer vaccine only).





Potential COVID-19 Vaccines

Pfizer/BioNTech

- 2 doses required, Commonwealth has purchased 10M doses
- Store at -70°; reactogenic; watch for anaphylaxis (11 per million doses); high efficacy
- Likely approval and in country mid-February 2021

Oxford/AstraZeneca

- 2 doses required, Commonwealth has purchased 53.8M doses
- Store at 2-8°; moderate efficacy
- Likely approval and in country March 2021

Novavax

- 2 doses required, Commonwealth has purchased 51M doses
- Store at 4-8°
- Undergoing Phase 3 clinical trials, if successful likely approval and in country June/July 2021





COVID-19 vaccine national roll-out strategy





COVIDSAFE

COVID-19 vaccine national roll-out strategy First priority populations

The Australian COVID-19 vaccination program will commence with priority populations including aged care and disability care residents and workers, frontline healthcare workers and quarantine and border workers.





COVIDSAFE

Priority frontline

healthcare workers



Phase 1a vaccination sites in NSW

- · Sydney
 - · Camperdown (Royal Prince Alfred)
 - Westmead
 - Liverpool
 - Hornsby*
 - Kogarah (St George)*
 - Nepean*
- Regional (primary hubs to be determined, with potential for outreach spokes)
 - Newcastle*
 - Wollongong*
 - Coffs Harbour*
 - Dubbo*
 - Wagga Wagga*
 - · Further primary regional hubs may be determined as required and feasible

ACT to assist with Queanbeyan and surrounding region





Vaccination clinic planning

Immunisation workforce

- · Not anticipated to be a rate-limiting step
- · At least 1,500 nurse immunisers in NSW Health; other nurses supporting under standing orders
- · Approximately 500 nurse immuniser scholarships provided
- 50 additional nurse immunisers to be employed through NSLHD (EOIs closed 10 January)
- Need to consider supporting staff including admin, security, crowd control, pharmacy, medical and plan to operate vaccination clinics 7 days per week.

Training and education

- · Vaccine storage and cold chain management education module (already live on HETI).
- NCIRS shoulder injury related to vaccination presentation (already live on NCIRS website).
- Multi-dose vial education module (due to go live 15 January 2021 on HETI and CEC website).
- Anaphylaxis education module (due to go live 15 January 2021 on HETI and CEC website).
- · eLearning platform on vaccination procedures (already live on MVEC website).
- NSW Health COVID-19 Vaccination Policy and Guidelines
 - · Vaccination Policy drafted.



COVID-19 Mass Vaccination Clinics Guideline drafted.

Health Hunter New England Local Health District



ICT enhancements

- Enhancements to VaxLink include:
 - Additional screens and reports to record COVID-19 vaccinations and report on vaccine uptake/refusal (likely live in February).
 - An interface capability with the Australian Immunisation Register (AIR) (likely go live week of 11 January).
 - Online consent and record management process (now live).
 - Interface to Vaxtracker to support active surveillance of adverse events following immunization (AEFI) (now live).
- Reviewing availability of iPads at proposed phase 1a vaccination clinic sites to support online registration and consent
- Processes for registration of non NSW Health staff underway to link with the Australian Immunisation Register (AIR)





RACF Preparation



- RACFs will be advised of their vaccination date/s and should ensure that maximum number of residents are available. There will be little room for changing or amending vaccination timetables. Consider utilizing sister facilities to help with staffing on the day
- Consents will be responsibility of RACF's and the usual GP's. A consent template has been developed and is available. If you are using your own template ensure consent is understood as being provided for the two doses of the same vaccine. Action these as quickly as possible
- <u>consent form</u>
- Visit the <u>Department of Health's website</u> for more information or to <u>read the consent form</u> <u>in other languages</u>
- RACFs will be responsible for communicating with residents, families, staff and other in-scope visitors in relation to the vaccine program arrangements especially GPs





RACF Preparation

- Workforce will bring or deliver prior -all the equipment and supplies including consumables.
- RACF's will need to provide appropriate space for the vaccinations.

Link to the Toolkit

COVID-19 vaccine aged care readiness toolkit

Training



Home > Initiatives and programs > COVID-19 vaccines

COVID-19 vaccination training program

Information about free and accredited training modules for people involved in the administration of COVID-19 vaccines

<u>COVID-19 vaccination training program</u>
 <u>Australian Government Department of Health</u>



Mass Clinics





Moderna's COVID-19 vaccine is administered at City College of San Francisco, the city's first mass vaccination site, on Jan. 22.







Supersites for COVID-19 vaccinations are opening in various locations across the country. Jon Cherry/Getty Images



Global snapshot

as of 29 January 2021



173

vaccine candidates in pre-clinical development



63

vaccine candidates in human clinical trials, including phase I, II and III



16 vaccine candidates in phase III clinical trials

http://ncirs.org.au/covid-19/covid-19-vaccine-development-landscape



Vaccine development







Vaccines in Phase 3



Phase III

Vaccine	Developer	Clinical trial in	Vaccine platform	Number of participants	Age range
ChAdOx1 nCoV-19	AdOx1 nCoV-19 University of Oxford		Viral vector	5,000	≥18 years
CoronaVac	Sinovac Biotech	Brazil	Inactivated	8,870	≥18 years
CoronaVac	Sinovac Biotech	Turkey	Inactivated	13,000	18-59 years
Unnamed	Wuhan Institute of Biological Products	United Arab Emirates, Bahrain, Egypt and Jordan	Inactivated	45,000	≥18 years
Unnamed	Beijing Institute of Biological Products	United Arab Emirates, Bahrain, Egypt and Jordan	Inactivated	45,000	≥18 years
Unnamed	Beijing Institute of Biological Products	Argentina	Inactivated	3,000	≥18÷ 85 years
mRNA-1273	Moderna	USA	RNA	30,000	≥18 years
BNT162b2	BioNTech/Pfizer	USA	RNA	43,998	≥18 years
CoronaVac	Sinovac Biotech	Indonesia	Inactivated	1,620	18-59 years
AZD1222/ChAdOx1 nCoV-19	AstraZeneca/University of Oxford	USA	Viral vector	40,051	18- 130 years
Gam-COVID-Vac	Gamaleya Research Institute	Russia	Viral vector	40,000	18-111 years
Ad5-nCoV	CanSino Biologics	Russia	Viral vector	500	18-85 years
Ad5-nCoV	CanSino Biologics	Pakistan	viral vector	40,000	≥18 years
Ad26.CoV2.S	Janssen	Three continents	viral vector	60,000	≥18 years
NVX-CoV2373	Novavax	ик	Protein	10,000	18-84 years
Gam-COVID-Vac	Gamaleya Research Institute	Belarus	Viral vector	100	18-60 years
Unnamed	Beijing and Wuhan Institute of Biological Products	Peru	Inactivated	6,000	18-60 years
CoronaVac	Sinovac Biotech	China	Inactivated	1,040	≥18 vears



VACCINE BASICS: HOW WE DEVELOP IMMUNITY The body's adaptive immune system can learn to recognize new, invading pathogens, such as the coronavirus SARS-CoV-2. Coronavirus



The race for coronavirus vaccines: a graphical guide

Eight ways in which scientists hope to provide immunity to SARS-CoV-2.

Ewen Callaway

https://www.nature.com/articles/d41586-020-01221-y





Graphics: Nik Spencer/Nature


Vaccinology







Neutralising Antibodies







Vaccine platforms being employed for SARS-CoV-2 vaccine design





Flanagan KL, Best E, Crawford NW, Giles M, Koirala A, Macartney K, Russell F, Teh BW and Wen SCH (2020) Progress and Pitfalls in the Quest for Effective SARS-CoV-2 (COVID-19) Vaccines. Front. Immunol. 11:579250. doi: 10.3389/fimmu.2020.579250

Types of Vaccines



AN ARRAY OF VACCINES



* Other efforts include testing whether existing vaccines against poliovirus or tuberculosis could help to fight SARS-CoV-2 by eliciting a general immune response (rather than specific adaptive immunity), or whether certain immune cells could be genetically modified to target the virus.

onature

Sources: *Nature* analysis based on: WHO COVID-19 Vaccine Landscape/Milken Institute COVID-19 Treatment and Vaccine Tracker/T. Thanh Le *et al. Nature Rev. Drug. Disc.* http://doi.org/ggrnbr (2020)/F. Amanat & F. Krammer *Immunity* **52**, 583–589 (2020)/W. Shang *et al. npj Vaccines* **5**, 18 (2020).



Vaccine platforms being employed for SARS-CoV-2 vaccine design





Novavax

GOVERNMENT



Similar to HPV vaccine – harvesting viral proteins





Novavax







Novavax (NVX-CoV2373)







Vaccine platforms being employed for SARS-CoV-2 vaccine design







mRNA vaccines



Diagram: Callaway, E. (2020). The race for coronavirus vaccines: a graphical guide. *Nature*, <u>https://www.nature.com/articles/d41586-020-01221-y</u> Image from the Noun Project



Deep freezers





A worker passes a line of freezers holding coronavirus disease (COVID-19) vaccine candidate BNT162b2 at a Pfizer facility in Puurs. Belgium in an undated photograph. Pfizer/Handout via REUTERS

https://www.reuters.com/article/us-health-coronavirus-freezers/u-s-states-race-to-buy-ultra-cold-vaccine-freezers-fueling-supply-worries-idINKBN27T2S6



Pfizer's thermal shipper

Health

Hunter New England Local Health District





https://edition.cnn.com/2020/11/10/health/pfizer-vaccine-distribution-cold-chain/index.html

Pizza Boxes





New stability data show the BioNTech/Pfizer vaccine can be kept at normal medical freezer temperatures of minus 15C to minus 25C for up to two weeks © Ronny Hartmann/AFP/Getty

BioNTech/Pfizer Covid vaccine no longer needs ultra-cold storage | Financial Times (ft.com)







health.nsw.gov.au

Management of COVID-19 Pfizer (COMIRNATY™) vaccine from refrigerator to administrationo mRNA-1273

<u>/accine against SARS-CoV-2 | NEJM</u>

Last updated: 19 February 2021

Responsibility

Staff preparing the refrigerated COMIRNATY[™] vaccine for administration must follow this procedure. When working in pairs, it is the responsibility of both people to continue to follow this procedure and observe all local COVID-19 precautions, including maintaining social distancing where possible.

Overview

The COVID-19 Pfizer/BioNTech (COMIRNATY[™]) vaccine must be thawed before use following removal from an ultra-low temperature storage environment. Refer to <u>Management of COVID-19 Pfizer (COMIRNATY[™])</u> vaccine from freezer to fridge for information on this procedure.



Vaccine platforms being employed for SARS-CoV-2 vaccine design









health.nsw.gov.au

COVID-19 Vaccination Program Procedures

Management of COVID-19 Vaccine AstraZeneca (ChAdOx1-S) from refrigerator to administration

Last updated: 9 March 2021

Purpose

This Procedure describes the process of receipting, storing, transporting and drawing up the COVID-19 Vaccine AstraZeneca (ChAdOx1-S) in NSW Health clinics.

This procedure MUST NOT be used for any other COVID-19 vaccine.

Responsibility

Staff preparing the refrigerated COVID-19 Vaccine AstraZeneca (ChAdOx1-S) for administration must follow this procedure. When working in pairs, it is the responsibility of both people to continue to follow this procedure and observe all local COVID-19 precautions, including maintaining social distancing where possible.



Astra Zeneca Covid-19 Vaccine





Multi Dose Vial



Vaccination with the COVID-19 Vaccine AstraZeneca will not affect a polymerase chain reaction (PCR) swab test used to detect COVID-19. Results may be altered for serum antibody tests if they detect the spike protein antibodies (AstraZeneca, 2021).

Each multi-dose vial (MDV) contains either **4 mL or 5 mL** of liquid depending on where the vial was manufactured. Each dose is 0.5 mL, meaning there are either **8 or 10 doses** in each MDV. There are 10 MDVs in a box (AstraZeneca, 2021).

Supply Route	Dose volume	Vial Size	Doses per Vial
Local CSL	0.5 mL	5 mL	10 doses per vial
Imported Stock type 1	0.5 mL	5 mL	10 doses per vial
Imported Stock type 2	<u>0.5 mL</u>	<u>4 mL</u>	<u>8 doses per vial</u>







The stability of the vaccine after drawing it up into a syringe has not been studied and it therefore should be **administered immediately after being drawn up** (AstraZeneca Pharmaceuticals LP, 2021).



Thermostability



The vaccine can be stored in cold chain conditions of +2°C to +8°C for a **maximum of 6 months** as per the expiry date printed on the vial. **Do not freeze the vaccine**.

Once opened, the MDV can be used until one of the following has been reached:



(AstraZeneca, 2021)

If either of these time limits have been reached, then the vial must be discarded in the



Chimp adenovirus (ChAdOx1 nCoV-19) S protein (now called AZD1222

A Piece of the Coronavirus

The SARS-CoV-2 virus is <u>studded with proteins</u> that it uses to enter human cells. These so-called spike proteins make a tempting target for potential <u>vaccines</u> and <u>treatments</u>.



The Oxford-AstraZeneca vaccine is based on the virus's <u>genetic</u> <u>instructions</u> for building the spike protein. But unlike the <u>Pfizer-</u> <u>BioNTech</u> and <u>Moderna</u> vaccines, which store the instructions in single-stranded RNA, the Oxford vaccine uses double-stranded DNA.









Building Spike Proteins











London, UK

Cite this as: *BMJ* 2021;372:n326 http://dx.doi.org/10.1136/bmj.n326 Published: 03 February 2021

Covid-19: New data on Oxford AstraZeneca vaccine backs 12 week dosing interval

Jacqui Wise

The UK's approach of leaving an interval of three months between doses of the Oxford AstraZeneca covid-19 vaccine has been supported by new data, with the Oxford University researchers also saying the vaccine "may have a substantial impact on transmission."

The paper, a preprint currently under review at the *Lancet*, is an analysis of additional data from trials involving 17 177 participants in the UK, Brazil, and South Africa.¹ It includes the results of a further month of data collection with 332 cases of symptomatic covid-19—an additional 201 cases than were previously reported.²

reassures us that people are protected from 22 days after a single dose of the vaccine."

Commenting on the study, Paul Hunter, professor in medicine at the University of East Anglia, said, "Taking all this evidence together, the 12 week gap between first and second dose is clearly the better strategy as more people can be protected more quickly and the ultimate protective effect is greater. Given the poor efficacy at preventing asymptomatic infections, the vaccine will not stop transmission of covid but will still go a long way to reduce the R value and transmission because there will be far fewer symptomatic infections and people who are





- No COVID-19-related hospital admissions occurred in ChAdOx1 nCoV-19 recipients, whereas ten (two of which were severe) occurred in the control groups.
- Vaccine efficacy for the prespecified primary analysis against the primary endpoint of COVID-19 occurring more than 14 days after the second dose was 70.4%

Oxford–AstraZeneca COVID-19 vaccine efficacy - The Lancet



VOLUME 397, ISSUE 10269, P72-74, JANUARY 09, 2021

Pfizer Vaccine: NEJM paper, dec, 2020.

- Enrolled from age 16 up, 21,700 each arm (placebo arm v vax)
- 2 doses, 21 days apart, transport at -70°C, but stable at 4°C for 6 days
- Assessed @ 7 days after doses 1 & 2.
- 9 infections vax group, 169 in placebo (95% efficacy), <effect elderly (~82%)
- 10 cases of severe COVID, but only 1/10 vax recipient (protect severe Δ)
- Lab studies suggest Abs will block UK/SA variants (no human data yet)
 Limits of study: Most patients USA; effect measure least 7 days after 2nd dose.
 95% efficacy at this time; 50% if measure 1wk after first dose
 <u>Side effects</u>
 - After 1,893,360 doses of Pfizer-BioNTech in USA, 4,393 (0.2%) Sig adverse events.
- 175 of the 4,393 reported severe allergy: 21 were anaphylaxis (11/million) at review
- All occurred within 13 minutes, no deaths
- Most often fatigue, fever, headache myalgia, local reactN at injection site (~50%)



Early effectiveness of COVID-19 vaccination with BNT162b2 mRNA vaccine and ChAdOx1 adenovirus vector vaccine on symptomatic disease, hospitalisations and mortality in older adults in England

Jamie Lopez Bernal et al

- Conclusion
- Vaccination with either a single dose of BNT162b2 or ChAdOx1 COVID-19 vaccination was associated with a significant reduction in symptomatic SARS-CoV2 positive cases in older adults with even greater protection against severe disease. Both vaccines show similar effects. medRxiv preprint doi: maintained for the duration of follow-up (>6 weeks).
- A second dose of BNT162b2 provides further protection against symptomatic disease but second doses of ChAdOx1 have not yet been rolled out in England. There is a clear effect of the vaccines against the UK variant of concern.









Hunter New England Local Health District

Varients



Name (Pangolin)	Name (Nextstrain)	First Detected	Cases in the US	Countries Reporting Cases	Key Mutations	Transmissibility Rate
B.1.1.7	20I/501Y.V1	United Kingdom	Y	70	 69/70 deletion 144Y deletion N501Y A570D D614G P681H 	~50% increase ^{14,15}
P.1	20J/501Y.V3	Japan/ Brazil	Y	>4	 E484K K417N/T N501Y D614G 	Not determined
B.1.351 ⊳	20H/501.V2	South Africa	Y	>30	 K417N E484K N501Y D614G 	Not determined



Immune responses target 2 main areas of the spike protein:

- Receptor-binding domain (RBD)
- N-terminal domain





Prof Salim Abdool Karim Scientific panel discussion on the new variant, 501Y.V2. - YouTube





UK Variant









Adverse Events



The following list identifies the frequency of very common adverse events following immunisation (AEFI) in completed clinical trials:

- Injection site tenderness (>60%), pain (>50%), warmth (>15%) and itch (>10%).
- Headache (>50%).
- Fatigue (>50%).
- Myalgia/muscle pain (>40%).
- Malaise (>40%).
- Pyrexia/fever and chills (>30%).
- Arthralgia/joint pain (>20%).
- Nausea (>20%).

Most common AEFIs are mild and self-limiting for 1 to 2 days. To help manage pain and swelling, a cold compress or icepack wrapped in a cloth can be used on the injection site. Paracetamol and ibuprofen are not routinely recommended to be taken post COVID-19 vaccination. However, they can be taken to alleviate pain and swelling adverse events if required (ATAGI, 2021c).

(AstraZeneca, 2021)



Receive vaccine & Stock – report Online



Australian Government Oxford-AstraZeneca Vaccine Acceptance Form

Overview

This 'AZ Vaccine Acceptance Form' has been developed for locations (Sites), which receive deliveries of AstraZeneca vaccines (AZ Vaccines) to complete when taking delivery of AZ Vaccine to ensure that:

- AZ Vaccines are received, stored and handled appropriately
- · key obligations are managed,
- · the AZ Vaccines are delivered as expected, and
- the Department of Health (Health) is notified of receipt of the AZ Vaccines or any issues that arise.

Responsibility

This AZ Vaccine Acceptance Form must be completed at the time that you receive the AZ Vaccine at the Site and sent to Health by no later than 9pm (local time) on the day of delivery. However, if there are any issues with the AZ Vaccines delivered, Health must be notified immediately (and in any event, within 2 hours of the delivery) by calling the Vaccine Operations Centre on 1800 318 208 and then by providing this AZ Vaccine Acceptance Form by email to COVID19VaccineAcceptance@health.gov.au as soon as possible following that call.

To complete this AstraZeneca Vaccine Acceptance Form, you must complete every section of this form.

Complete Form

<u>Click to start completing the AstraZeneca Vaccine</u> <u>Acceptance Form</u> >

Closes 23 Mar 2022 Opened 1 Mar 2021

Contact

1800 318 208 COVID19VaccineAcceptance@he alth.gov.au

Australian Government Vaccine Stock Management Form (For Pfizer and AZ)

Overview

Australian Government

Consultation Hub Find Consultations We Asked, You Said, We Did

This Vaccine Stock Management Form should be completed no later than 9 pm each day (local time) during the period that a vaccine is held by an administration site. It is critical that cold-chain storage and handling requirements for the Vaccines are maintained at all times and are not breached during the stocktake process.

If there is any issue, Health must be notified immediately (and in any event, within 2 hours of the delivery) by calling the Vaccine Operations Centre on 1800 318 208 and then by completing this Stock Management Form as soon as possible following that call. If you have any other queries (not urgent) regarding stock management, please email the Vaccine Operations Centre COVID19VaccineStock@health.gov.au Closes 16 Feb 2022 Opened 18 Feb 2021

Search consultations

Contact 1800 318 208 COVID19VaccineStock@health.go v.au

Complete Form

<u>Click to start completing the Vaccine Stock</u> <u>Management Form</u> >





Australian Government Vaccine Wastage Report

Overview

This form must only be completed where a wastage occured exceed the threshold (5 or more vials in one incident). All other wastage must be reported on the daily stock management form. Please read further information below.

In the event of a potential wastage incident, or actual wastage incident (e.g. damaged vials, breach of cold chain requirements), that **exceeds the threshold** of 5 or more vials at a time, each Administration Site or other location which receives deliveries of Vaccines (Pfizer Hub) must notify Health immediately by calling VOC on 1800 318 208 (including, if the wastage occurred in transit, indicating whether the Product was delivered to the Pfizer Hub or Administration Site).

Following the call to VOC, please complete this *Vaccine Wastage Report* with any details of the call with Health and submitting it immediately.

If you have any other queries (not urgent) regarding vaccine wastage, please email the Vaccine Operations Centre COVID19VaccineWastage@health.gov.au

Complete Form

<u>Click to start completing the Vaccine Wastage</u> <u>Report</u> >

Closes 16 Feb 2022 Opened 19 Feb 2021

Contact 1800 318 208 COVID19VaccineWastage@healt h.gov.au





PRODA and Health Professional Online Services (HPOS)



To access the AIR through the hosting site, Health Professional Online Services (HPOS), you will need to first sign up for a free Provider Digital Access (PRODA) account for individuals (as of 7 December 2020).

Please click the 'Start' button below for further information.

START >

PRODA and Health Professional Online Services (HPOS)

A PRODA authentication login can also be used to access other health provider services that you are eligible for, including but not limited to:

- Medicare online.
- Pharmaceutical Benefits Scheme (PBS) online.
- Aged Care Provider Portal.
- Practice Incentives Program (PIP).

Use your PRODA account to log in to the AIR through HPOS using <u>this link</u>. Confirm the person's details and check their vaccination history. After the new vaccination encounter has been entered, double-check the information.



Vaccine Safety – Phase 4





Last updated 13/11/2020

event, including...

0.5%

who reported taking their child to a doctor or emergency

department in the days after vaccination.

The adverse events they reported were similar to the

types of adverse events reported overall



75,401 Parents/carers responded to an SMS about their child's health a few days after their HPV vaccinations.





These symptoms are known to occur after vaccination. They are generally mild and short-lived.





Active surveillance

AusVaxSafety is an active vaccine safety surveillance system that complements the TGA's enhanced safety surveillance activities. Active vaccine safety surveillance uses SMS and a short survey to collect reports of AEFI directly from a subset of people receiving the vaccines. AusVaxSafety is an Australian Government-funded system that shares its findings with the TGA to assist our safety investigations and responses.

AusVaxSafety surveillance data to 28 February 2021:

There were 11,079 surveys sent in six of the eight states and territories, with 7397 people responding (67% response rate).

Of those who responded:

- 64% reported no adverse event
- 36% reported one or more adverse events
- 0.7% reported visiting a doctor or emergency department as a result of their adverse event.

The most commonly reported reactions were:

- injection site pain
- fatigue
- headache.



COVID-19 vaccine weekly safety report #1 - 03-03-2021 Therapeutic Goods Administration (TGA)





AusVaxSafety's ACTIVE follow-up after your COVID-19 vaccination



AusVaxSafety monitoring vaccine safety of COVID-19 vaccines

AusVaxSafety is a national system for monitoring vaccine safety in Australia. In partnership with the Australian state and territory health departments, AusVaxSafety is following up people who receive a COVID-19 vaccine by sending them an SMS or email with a short survey that asks if they experienced any adverse event following vaccination.





Sign up now to participate at this clinic by scanning the QR code

Your participation will contribute to the national COVID-19 vaccine safety surveillance that AusVaxSafety is conducting. Depending on your survey responses, your state/territory health department may contact you to collect more details. While your state/territory health department will have your personal data from the survey, it will be de-identified before being included in the national surveillance data.

Visit: www.ausvaxsafety.org.au to read more about AusVaxSafety







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DEMO USE ONLY

HNE Demo Clinic uses Vaxtracker to monitor COVID vaccine safety.

Please scan the code using your camera to register for follow-up.



You will get an SMS or email link to the first survey in three days.



HNE Demo Clinic COVID-19 (NSW) Static Signup Poster





C REUTERS

Australia health minister in hospital after vaccination but link ruled out



Australian Minister of Environment Greg Hunt signs the Paris Agreement on climate change held at the United Nations Headquarters in New York





- Combining data from both trials, among nearly 40000 vaccine arm participants, there were seven Bell's palsy cases compared with one Bell's palsy case among placebo arm participants.
- This estimated rate ratio of roughly 7.0, suggests vaccination might be associated with Bell's palsy (p=0.07).
- Bell's palsy and SARS-CoV-2 vaccines (thelancet.com)



Figure 1. Delayed Cutaneous Reactions to mRNA-1273 Vaccine.





Delayed Large Local Reactions to mRNA-1273 Vaccine against SARS-CoV-2 | NEJM





Commentary

Chilblain-like lesions on feet and hands during the COVID-19 Pandemic

Nerea Landa¹, MD, Marta Mendieta-Eckert¹, MD Pablo Fonda-Pascual², MD and Teresa Aguirre³, MD

¹Department of Dermatology, Dermitek Clinic - Grupo stop, Bilbao, Spain; ²Department of Dermatology, Hospital Gómez Ulla, Madrid, Spain; and ³Primary Care Physician, Centro Bombero Echaniz, Bilbao, Spain







Figure 1 (a) chilblain lesions on toes (b) detail of the toe lesions (c) similar lesions on heel

AEFI Reporting to PHU



Summary of reporting requirements and pathways for adverse events identified following COVID-19 vaccination





TGA use only Date report received:

Notification ID:

This form, when completed, will be classified as 'For official use only'. For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

National Adverse Events Following Immunisation (AEFI) reporting form

Vaccinated person's details					
Personal details					
Sumame:					
First name:					
Gender:	Male Female Unknown				
Date of Birth:		or			
Age:	Months	or	Years		
Street address:					
Suburb:					
State:					
Postcode:					
Name of parent/guardian: (if relevant)					
Phone: Landline (inc. area code) or mobile					





Co-led by Gavi, CEPI and WHO

Goal:

- To vaccinate the most vulnerable 20% of the population of every country that participates, regardless of income level by the end of 2021
- To deliver two billion doses of safe, effective vaccines that has passed regulatory approval and/or WHO prequalification by 2021

There are:

- 92 COVAX AMC-eligible countries
- 78 potentially self-financing countries that have expressed written interest in the COVAX facility



https://www.gavi.org/covid19/covax-facility

Australia's commitments to the COVAX Facility

- The Australian Government has made 2 financial commitments to Gavi's COVAX Facility for the supply of safe and effective COVID-19 vaccines:
- An upfront payment of \$123.2 million to allow the purchase of over 25,000,000 doses of COVID-19 vaccines for the Australian population. This would be sufficient for 50 percent of the population to receive a 2 dose regimen.
- A further \$80 million to support vaccine access for up to 94 lowerincome countries through the Facility's Advanced Market Commitment.

