

# CONSENT

## Valid consent



# Valid consent can be defined as:

- The Voluntary agreement by an individual to a proposed procedure, given after appropriate and reliable information about the procedure.

Includes –

- The potential risks and benefits that have been conveyed to the individual

# Valid Consent

## - Legally valid

To be legally valid the following elements must be present:

- It must be given by a person with legal capacity, and of sufficient intellectual capacity to understand the implications of being vaccinated.
- It must be given voluntarily.
- It can only be given after the relevant vaccine(s) and their potential risks and benefits have been explained to the individual.

- The individual must have sufficient opportunity to seek further details or explanations about the vaccine(s) and/or their administration
- Consent should be obtained before each vaccination, once it has been established that there are no medical conditions that contraindicate vaccination.

# Consent on behalf of a child or adolescent

- In general, a parent or legal guardian of a child has the authority to consent to vaccination of a child.
- A child in this context is defined as being under the age of 18 years in all States and Territories except New South Wales, where the age is 14 years, and in South Australia and the Northern Territory, where the age is 16 years.
- If the child is of sufficient age and maturity to understand the proposed procedure and the risks and benefits associated with same, children at younger ages may be able to provide consent for procedures such as vaccination.
- Gillick competence

# Consent on behalf of people with impaired decision-making ability

- A responsible adult family member, preferably with authority to make medical decisions, may give consent for vaccination of an adult with a significant disability.
- For example, this may occur for influenza vaccination of an elderly person with dementia.

# Resources to help communicate the risks and benefits of vaccines

- Plain language should be used in communicating information about vaccines and their use to an individual. The individual must be allowed to ask for further information and have time to make a decision about whether to consent or not.
- It is preferable that printed information is available to supplement any verbal explanations.
- The summary table *Comparison of the effects of diseases and the side effects of vaccines* inside the back cover of **The Australian Immunisation Handbook 9<sup>th</sup> ed.** provides some basic information necessary to communicate the risks and benefits of vaccination.

More detailed information concerning vaccines and their use is available from the following sources:

**[www.immunise.health.gov.au](http://www.immunise.health.gov.au)**

- The Immunise Australia website includes ‘Common questions and answers (fact sheets)’, ‘Understanding childhood immunisation’ and links to State and Territory Health Department websites. Several of these sites offer multilingual fact sheets

**[www.ncirs.edu.au](http://www.ncirs.edu.au)**

- The National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases website includes fact sheets related to specific vaccines, vaccine-preventable diseases and vaccine safety

**Australian Immunisation Handbook 9<sup>th</sup> ed.**

- Appendix 5

# Pre Vaccination Checklist

- available from your Division of General Practice

## PRE-VACCINATION CHECKLIST

The following information is needed to assess whether a person/child can be vaccinated and, if so, which vaccines they may require.

### PLEASE TELL THE IMMUNISATION PROVIDER IF THE PERSON TO BE VACCINATED:

- is unwell today;
- has a disease which lowers immunity (eg. leukaemia, cancer, HIV/AIDS) or is having treatment which lowers immunity (eg. oral steroid medicines such as cortisone and prednisone, radiotherapy, chemotherapy);
- has had a severe reaction following any vaccine;
- has any severe allergies (to anything);
- has had any vaccine within the last month;
- has had an injection of immunoglobulin, received any blood products or a whole blood transfusion within the last 12 months;
- is pregnant;
- has a past history of Guillain-Barré Syndrome;
- was a preterm infant;
- has a chronic illness;
- has a bleeding disorder.

### A DIFFERENT VACCINATION SCHEDULE MAY BE RECOMMENDED IF THE PERSON TO BE VACCINATED:

- identifies as an Aboriginal or Torres Strait Islander person;
- does not have a functioning spleen;
- is planning a pregnancy or anticipating parenthood;
- is a parent, grandparent or carer of a newborn;
- lives with someone who has a disease which lowers immunity, or lives with someone who is having treatment which lowers immunity.

### BEFORE ANY VACCINATION TAKES PLACE, THE IMMUNISATION PROVIDER WILL ASK YOU:

- Do you understand the information provided to you about immunisation?
- Do you need more information to decide whether to proceed?
- Did you bring your/your child's vaccination record with you?

It is important for you to receive a personal record of your or your child's injections. If you do not have a record, ask your immunisation provider to give you one. Bring this record with you every time you or your child visit for vaccination. Make sure your doctor/nurse records all vaccinations on it. You may be asked to show this record to your child's childcare, preschool or school.

FOR FURTHER INFORMATION CONTACT THE TASMANIAN DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC AND ENVIRONMENTAL HEALTH SERVICE  
FREE CALL 1800 671 738



This resource is based on information contained within The Australian Immunisation Handbook 9<sup>th</sup> Edition, 2008 and produced with funding provided by the Australian Government Department of Health and Ageing

## COMPARISON OF EFFECTS OF VACCINES AND DISEASES

DISEASE	EFFECTS OF DISEASE	SIDE EFFECTS OF VACCINATION
<b>Diphtheria</b> - contagious bacteria spread by droplets. Causes severe throat and breathing difficulties.	About 1 in 15 contacts die. The bacteria release a toxin which can produce severe paralysis and heart failure.	DTaP/dTcP vaccine - about 1 in 10 has local inflammation or fever. Booster doses of DTaP may occasionally be associated with extreme diarrhoeal/colic/irritability of the tummy, but this resolves completely within a few days. Serious adverse events are very rare.
<b>Hepatitis B</b> - virus spread mainly by blood, sexual contact or from mother to newborn baby) causes acute hepatitis or chronic carriage.	About 1 in 4 chronic carriers will develop cirrhosis or liver cancer.	About 1 in 15 will have injection site pain and 1 in 100 will have fever. Anaphylaxis occurs in about 1 in 600 000.
<b>Hib</b> - contagious bacteria spread by respiratory droplets. Causes meningitis, septicaemia (respiratory obstruction), otitis media, osteomyelitis.	About 1 in 20 meningitis patients die and 1 in 4 survivors have permanent brain or nerve damage. About 1 in 100 otitis media patients die.	About 1 in 20 has discomfort or local inflammation. About 1 in 50 has fever.
<b>Hence papillomavirus (HPV)</b> - virus spread mainly via sexual contact	About 1 in 2 of cervical cancers worldwide have been associated with HPV16 and 1 in 10 with HPV18.	About 6 in 10 will have pain and 2 in 10 will have swelling of the site of injection and may occasionally headache, fever and nausea.
<b>Influenza</b> - contagious virus spread by respiratory droplets. Causes fever, muscle and joint pains, pneumonia.	Causes increased hospitalisation in the elderly. High-risk groups include the elderly, diabetics and alcoholics.	About 1 in 10 have local reactions. Guillain-Barré syndrome occurs in about 1 in 1 million.
<b>Meningitis</b> - highly infectious virus spread by droplets. Causes fever, cough, rash.	1 in 15 children with meningitis develops pneumonia and 1 in 1000 develops epilepsy (brain inflammation). For every 10 children who develop meningitis, 1 dies and 4 have permanent brain damage. About 1 in 100 000 develops SGB (brain degeneration), which is always fatal.	About 1 in 10 has discomfort, local inflammation or fever. About 1 in 20 develops a rash, which is non-infectious. Fewer than 1 in 1 million recipients may develop encephalitis (inflammation of the brain).
<b>Haemorrhagic infections</b> - bacteria spread by respiratory droplets. Causes septicaemia (infection of the blood stream) and meningitis (infection of the tissues surrounding the brain).	About 1 in 10 patients die. Of those that survive, 1 in 20 has severe skin scarring or loss of limbs, and 1 in 20 has severe brain damage.	Conjunctiva vaccine - About 1 in 10 has local inflammation, fever, irritability, nausea or headache.
<b>Mumps</b> - contagious virus spread by saliva. Causes swollen neck and salivary glands, fever.	1 in 200 children develop encephalitis. 1 in 5 males post puberty develop inflammation of the testes. Occasionally mumps causes infertility or deafness.	1 in 100 vaccine recipients may develop swelling of the salivary glands. 1 in 3 million recipients develop mild encephalitis.
<b>Pertussis</b> - contagious bacteria spread by respiratory droplets. Causes whooping cough and vomiting, lasting up to 3 months.	About 1 in 200 whooping cough patients under the age of 6 months die from pneumonia or brain damage.	As for DTaP/dTcP vaccine (see diphtheria).
<b>Preventable infections</b> - bacteria spread by respiratory droplets. Causes meningitis, meningitis and occasionally other infections.	About 1 in 10 meningitis patients die.	7dPCV - About 1 in 10 has local reaction or fever. 23vPPV - about 1 in 2 has a local reaction.
<b>Poliomyelitis</b> - contagious virus spread by faeces and saliva. Causes fever, headache, vomiting and may progress to paralysis.	While many infections cause no symptoms, about 1 in 20 hospitalised patients die and 1 in 2 patients who survive is permanently paralysed.	Local redness, pain and swelling of the site of injection are common. Up to 1 in 10 has fever, crying, and decreased appetite.
<b>Rotavirus</b> - virus spread by faecal-oral route. Causes gastroenteritis which can be severe.	In children <5 years of age, rotavirus infections in Australia account for approximately 10 000 hospitalisations every year; approximately 115 000 children visit a GP and approximately 22 000 children require an Emergency Department visit. These may range from mild, watery diarrhoea of limited duration to severe dehydrating diarrhoea and fever which can result in death.	1-3 in 1 hundred vaccine recipients may develop diarrhoea or vomiting in the week following vaccine administration.
<b>Rubella</b> - contagious virus spread by droplets. Causes fever, rash, swollen glands, but causes severe malformation to babies of infected pregnant women.	About 5 in 10 patients develop a rash and painful swollen glands. 5 in 10 adolescents and adults have painful joints. 1 in 3000 develops thrombocytopenia (bleeding) and 1 in 6000 develops inflammation of the brain. 9 in 10 babies infected during the first 10 weeks after conception will have a major congenital abnormality (such as deafness, blindness, or heart defects).	About 1 in 10 has discomfort, local inflammation, or fever. About 1 in 20 has swollen glands, stiff neck, or joint pain. About 1 in 20 has a rash, which is non-infectious. Thrombocytopenia (bleeding or bruising) occurs after a first dose of MMR or a rate of 1 in 20 500.
<b>Tetanus</b> - caused by toxin of bacteria in soil. Causes painful muscle spasms, convulsions, lockjaw.	About 2 in 100 patients die. The risk is greatest for the very young or old.	As for DTaP vaccine (see diphtheria).
<b>Varicella (chickenpox)</b> - highly contagious virus. Causes low-grade fever and vesicular rash. Reactivation of the virus later in life causes herpes zoster (shingles).	1 in 100 000 patients develop encephalitis (brain inflammation). About 2 in 100 000 patients die. Infection during pregnancy can result in congenital malformations in the baby. Onset of infection in the mother from 5 days before to 2 days after delivery results in severe infection in the newborn baby in up to one-third of cases.	About 1 in 5 has a local reaction or fever. A mild varicella-like rash may develop in 2-5 per 100 recipients.

Source: The Australian Immunisation Handbook 9<sup>th</sup> Edition, 2008

# Evidence of consent

## General practice or public immunisation clinics

- Consent may be given either in writing or verbally, according to the protocols of the health facility, but it must meet the criteria for valid consent.
- Evidence of verbal consent should be documented in the clinical records. If a standard procedure is routinely followed in a practice or clinic, then a stamp, a sticker or a provider's signature indicating that the routine procedure has been followed, may be used.

- For paperless medical records, a typed record of verbal consent may be made in the patient's file, or a copy of written consent scanned into the file
- Consent is often given and recorded at the first vaccination visit
- Explicit verbal consent is required before subsequent vaccinations even when written consent has been given at previous vaccination encounters