Operational Directive

**Enquiries to:** Communicable Disease Control Directorate

**OD number:** OD: 0600/15

**Phone number:** 9388 4863

**Date:** 13 May 2015

**Supersedes:** OD 0423/13 (13/03/2013)

**File No:** F-AA-13121

**Subject:** Influenza and Pertussis Vaccinations for Pregnant Women

This operational directive applies to all public metropolitan and regional facilities where women attend for antenatal care.

The purpose of this Operational Directive is to advise Department of Health (DoH) staff that all pregnant women should be offered influenza vaccination and pertussis-containing vaccine (dTpa) as part of routine antenatal care.

While private hospitals are not required to follow DoH Operational Directives it is strongly recommended that private hospitals follow this guidance because pregnant women are at increased risk of serious illness due to influenza. Vaccination given during the mothers pregnancy can reduce the risk of pertussis and influenza infection among newborns.

Professor Bryant Stokes
A/DIRECTOR GENERAL
DEPARTMENT OF HEALTH WA

This information is available in alternative formats for a person with a disability.
Influenza and Pertussis Vaccinations for Pregnant Women
Title: Influenza and Pertussis Vaccinations for Pregnant Women

1. Purpose

The purpose of this Operational Directive is to advise Department of Health (DoH) staff that all pregnant women should be offered influenza vaccination and pertussis-containing vaccine (dTpa) as part of routine antenatal care.

2. Background

Influenza Vaccine - The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) continues to strongly endorse routine vaccination of all pregnant women against influenza. This endorsement supports existing recommendations of the National Health and Medical Research Council and the Australian Technical Advisory Group on Immunisation.

Preventing influenza during pregnancy is an essential part of antenatal care because pregnant women are at increased risk of serious illness due to influenza.

Excess morbidity and mortality in pregnant women with influenza compared with non-pregnant women of similar age with influenza has been well documented.

The safety of influenza vaccination during pregnancy is well established; no study to date has shown an adverse consequence of inactivated influenza vaccine in pregnant women or their offspring.

Active placental transfer of maternal antibodies makes influenza vaccination during pregnancy a highly effective measure to protect infants from influenza during the first 6 months of life.

Both maternal and infant benefit is now proven, with one case of serious maternal or infant respiratory illness prevented for every 5 pregnant women who are vaccinated.

Pertussis Vaccine

The Australian Technical Advisory Group on Immunisation Practices recommends pertussis-containing vaccine (dTpa) be given as a single dose during the third trimester of each pregnancy. Administering pertussis vaccine to pregnant women has been recommended in the United Kingdom and United States since 2012.

Pertussis vaccination during pregnancy has been shown to be more effective in reducing the risk of pertussis in young infants than vaccination of the mother post partum. This added benefit is due to direct passive protection of the newborn by transplacental transfer of high levels of pertussis antibodies from the vaccinated woman to the fetus.
Vaccination is recommended with each pregnancy to provide maximal protection to every infant; this includes pregnancies which are closely spaced (e.g. <2 years). Vaccine-induced pertussis antibodies wane over time and the protective antibody level required in newborn infants is unknown. It is therefore possible that if a mother is not revaccinated during a subsequent pregnancy (even if closely spaced), her newborn will not be adequately protected against severe pertussis illness.

Studies have found no evidence of an increased risk of adverse pregnancy outcomes (such as stillbirth, pre-eclampsia, fetal distress, low birth weight or neonatal renal failure) related to pertussis vaccination during pregnancy. While dTpa vaccine is generally safe and well-tolerated in adults, there is a small risk that significant injection site reactions following subsequent doses might occur in some women who receive dTpa vaccines during successive closely spaced pregnancies. This low risk is considered to be balanced by the benefit to each infant of protection against pertussis.

3. Principles

In recognition of the benefits of protecting pregnant women and their newborns against influenza and pertussis the Department of Health recommends that all pregnant women should be offered influenza and dTpa vaccination as part of routine, comprehensive, antenatal care.

Influenza vaccination should ideally occur before the start of the influenza season, regardless of gestational age, but unvaccinated pregnant women can be immunized at any time vaccine is available. Influenza vaccine for the forthcoming season is usually available beginning in March-April of each year. The influenza vaccine can be administered to women during any stage of pregnancy, and while breast feeding.

As pertussis antibody levels do not peak until approximately 2 weeks after vaccination and active transport of maternal antibody to the fetus occurs predominantly from 30 weeks gestation onwards, the optimal time for dTpa vaccination is early in the third trimester (between 28 and 32 weeks). However, the vaccine can be given at any time during the third trimester up to delivery.

Pregnant women can be vaccinated with pertussis-containing vaccine and influenza vaccine at the same time during pregnancy, or at separate visits. To be optimally protected from influenza, women should get the influenza vaccine when it is available between March and July regardless of the trimester of pregnancy; however, vaccination with pertussis vaccine should wait until the third trimester.

Registered Nurses, Midwives, and Enrolled Nurses, are authorised to administer influenza vaccine and pertussis vaccine (dTpa) under the direction of the medical practitioner responsible for the care of the patient, in accordance with existing institutional antenatal care policies.

Patient education materials regarding influenza and pertussis vaccination in pregnancy are available from the Department of Health and can assist you in obtaining informed consent (Appendix 1-2).
4. **Obtaining influenza and pertussis vaccines for use in antenatal care**

Government-procured influenza and pertussis-containing vaccines (dTPa) are offered at no cost to all pregnant women in Western Australia.

To receive influenza and/or pertussis vaccine, pregnant women should visit their local doctor, antenatal clinic or their immunisation provider (e.g. community health immunisation clinics). It is important to note that although the vaccines are provided at no cost, a consultation fee may apply in private practice.

5. **Reporting requirements**

To comply with quality assurance monitoring, all WA Department of Health facilities must ensure that vaccines administered to pregnant women in antenatal clinics are recorded on the *Antenatal Vaccination Authorisation and Consent Form* (Appendix 3) and faxed to CDCD 08 9388 4877. Vaccines administered to pregnant women in antenatal clinics should also be recorded in the patients hand held antenatal care record and the facility’s electronic patient record database, if there is one.

Private hospitals and clinics, including GP and Obstetrician practices, are requested to fax the *Antenatal Vaccination Follow-up Form* (Appendix 4) provided to them to CDCD at fax number: 08 9388 4877.

6. **Ordering vaccines**

Orders for influenza and pertussis vaccine for pregnant women can be placed via the on-line vaccine ordering system at [http://dhswaonline.csldirect.com.au](http://dhswaonline.csldirect.com.au)

WA Department of Health facilities that do not have access to the on-line ordering system can telephone the Communicable Disease Control Directorate on 9388 4835.

7. **References**


12. Eick, A.A., Timothy M. Uyeki, MD, MPH, MPP; Alexander Klimov, PhD; Henrietta Hall, MS; Raymond Reid, MD; Mathuram Santosham, MD; Katherine L. O'Brien. Maternal influenza vaccination and effect on influenza virus infection in young infants. Arch Pediatr Adolesc Med. 2011;165(2):104-111.


Influenza Vaccine in Pregnancy: what expectant mothers need to know

What is influenza?

Influenza, commonly known as “the flu”, is caused by a highly contagious virus spread primarily through coughing and sneezing. Symptoms of influenza usually occur one to three days after infection and may include sudden onset of fever, chills, cough, sore throat, headache, muscle aches, severe tiredness and loss of appetite. Complications may include pneumonia, worsening of other illnesses, and death.

Why should pregnant women be vaccinated against influenza?

The Australian Government and Royal Australian and New Zealand College of Obstetricians and Gynaecologists recommend that all pregnant women be offered vaccination against flu.

1. **To protect themselves** - Getting the flu can cause serious problems when you are pregnant. Even if you are generally healthy, changes in immune, heart, and lung functions during pregnancy make you more likely to get seriously ill from the flu. Pregnant women who get the flu are at higher risk of hospitalisation, and even death, than non-pregnant women. Severe illness in the pregnant mother can also be dangerous to her unborn baby because it increases the chance for serious problems such as premature labour and delivery.

2. **To protect their baby** - When you get your influenza vaccination, your body starts to make antibodies that help protect you against the flu. Antibodies can be passed on to your unborn baby, and help protect the baby for up to 6 months after he or she is born. This is important because babies younger than 6 months of age are too young to get an influenza vaccine. If you breastfeed your infant, antibodies made in response your influenza vaccination may also be passed in breast milk and provide additional protection to your newborn.

The World Health Organisation recommends that pregnant women should receive the highest priority for influenza vaccination. This recommendation is based on “compelling evidence of a substantial risk of severe disease in pregnant women, evidence that vaccine is effective against severe disease, and the evidence supporting secondary protection of infants under 6 months, in whom disease burden is also high.”

Is the influenza vaccine safe for pregnant women and their baby?

Yes. The influenza vaccine has been given safely to millions of pregnant women worldwide over many years. Influenza vaccinations have not been shown to cause harm to pregnant women or their babies. Multiple studies confirm normal growth and health in babies with no excess in birth defects, cancers or developmental problems including learning, hearing, speech and vision. Since 2012, the WA Department of Health has monitored the safety of influenza vaccine in pregnant women and has found no serious safety issues following vaccination.
Can I get ‘flu’ from the influenza vaccine?

Influenza vaccine contains proteins from three different types of influenza viruses representing the strains most likely to circulate each winter. Inactivated influenza vaccines cannot give you influenza illness because they do not contain live virus. Influenza vaccine is free for pregnant women through the National Immunisation Program.

When is the best time to have influenza vaccine during pregnancy?

The influenza vaccine can be given at any time during pregnancy. Protecting women during their second and third trimesters is a priority because this is the time when serious complications from influenza are more likely to occur.

Can there be side effects from inactivated influenza vaccine?

The most common side effects after flu vaccination are mild, such as tenderness, redness and/or swelling where the vaccination was given. Some people might have headache, muscle aches, fever, and nausea or feel tired. If these symptoms occur, they usually begin soon after the vaccination and last 1-2 days. None of the common side effects endanger the baby. Sometimes, vaccinations can cause serious problems like severe allergic reactions. Life-threatening allergic reactions to vaccines are very rare, but be sure to tell the person giving the vaccine if you have any severe allergies or if you have ever had a severe allergic reaction following a vaccination.

Are there people who should not get the influenza vaccine?

If you ever had a life-threatening allergic reaction after a dose of any influenza vaccine, OR if you have a severe allergy to any part of this vaccine, you should not get an influenza vaccine. Tell your doctor if you have any severe allergies.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty in breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

If you think you are having a severe allergic reaction or any other medical emergency that requires urgent attention, call 000 or go to the nearest hospital. Otherwise, call your doctor.

Can I get the influenza vaccine and pertussis vaccine at the same time?

Yes, you can get the pertussis vaccine and flu vaccine at the same time during your pregnancy. You can also get them at different visits.

What is the WA Health Department doing to assure the safety of vaccines given to pregnant women?

WA Health has a program to routinely monitor vaccinations provided to pregnant women. Talk to your provider if you would like to participate in this follow-up service.

Where can I get more information?

- Talk to your GP, Obstetrician or Midwife.
- Contact your local health department.
- Visit the WA Health website at www.healthywa.wa.gov.au
Pertussis Vaccine in Pregnancy: what expectant mothers need to know

What is pertussis?
Pertussis, also known as ‘Whooping Cough’, is a highly contagious bacterial disease that is easily spread by coughing and sneezing. It commonly causes bouts of severe coughing that can last for months. Pertussis infection can be especially severe in infants under 12 months of age, causing breathing problems, pneumonia, and sometimes death.

Why should pregnant women be vaccinated against pertussis?
Pertussis vaccination in pregnancy works in two ways:

1. **It helps protect the mother** – Pertussis vaccine reduces the risk of the mother catching whooping cough and passing it to her newborn baby. Parents are a common source of whooping cough infection for children under 12 months old.

2. **It helps protect the baby** – Babies born to mothers who have had a pertussis vaccine in pregnancy have higher levels of antibodies against the disease than babies whose mothers were not vaccinated. This is because the antibodies made by the mother in response to the vaccine are passed to her baby across the placenta soon after vaccination and until delivery. The mother’s antibodies can help protect the newborn during the first months of life when they are most vulnerable to severe pertussis infection and still too young to be vaccinated themselves.

When is the best time for a pregnant woman to be vaccinated against pertussis?
The Australian Technical Advisory Group on Immunisations recommends pertussis vaccine (dTpa) be given during the third trimester of every pregnancy, including pregnancies which are closely spaced (e.g. <2 years apart). The optimal time for pertussis vaccination is between 28-32 weeks of pregnancy, but the vaccine may be given at any time in the third trimester. Women who have received pertussis vaccine during or after a previous pregnancy should be re-vaccinated in the third trimester of their current pregnancy.

Is the pertussis vaccine safe in pregnancy?
Pertussis vaccine has been used routinely in pregnant women in the United Kingdom (UK) and the United States (US) since 2012 and careful monitoring of this practice indicates that the vaccine is safe for pregnant women and their unborn babies.

In addition, large studies from the US and the UK looking at birth outcomes following pertussis vaccination during pregnancy have found no evidence of increased risk for stillbirth, premature birth, death of the baby within 28 days of birth, foetal distress, caesarean delivery, or low birth weight.

Can I have the pertussis and flu vaccines at the same time?
Yes. You can get the pertussis vaccine and flu vaccine at the same time during your pregnancy. You can also get them at different visits. To be optimally protected from flu, you should get the flu vaccine when it is available between March and July regardless of what trimester of pregnancy you are in. However, you should wait to get the pertussis vaccine until you are in the third trimester.
Can I get whooping cough from the pertussis vaccine?

No. Pertussis vaccines cannot give you or your baby whooping cough because they do not contain any live bacteria. The pertussis vaccines used contain purified, inactivated parts of the pertussis bacteria that cause the disease along with inactive toxoids from the bacteria that cause tetanus and diphtheria. These proteins stimulate the immune system to make antibodies against whooping cough, tetanus and diphtheria, but cannot cause the disease itself.

Can there be side effects from pertussis vaccine in pregnancy?

With any medicine, including the diphtheria-tetanus and inactivated pertussis (dTpa) vaccine, there is a chance of side effects. These are usually minor, but serious reactions are also possible. Most side effects do not affect daily activities and get better on their own in a few days. Common mild side effects from the dTpa vaccine include redness, swelling, pain, and tenderness where the injection is given, body-ache, fatigue, or fever. Headache, nausea, vomiting, diarrhoea, stomach ache, and arm swelling have also been reported. More serious reactions like severe swelling, pain, and redness in the arm where the injection was given occur rarely.

A life-threatening allergic reaction can happen after any vaccine, including dTpa, but the estimated risk is less than 1 in a million vaccinations. Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty in breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after vaccination.

If you think you are having a severe allergic reaction or any other medical emergency that requires urgent attention, call 000 or go to the nearest hospital. Otherwise, call your doctor.

Are there people who should not get the pertussis vaccine?

If you ever had a life-threatening allergic reaction after a dose of any pertussis, tetanus, or diphtheria containing vaccine, OR if you have a severe allergy to any part of this vaccine, you should not get dTpa. Tell your doctor if you have any severe allergies.

What is the WA Health Department doing to assure the safety of vaccines given to pregnant women?

WA Health has a program to routinely monitor vaccinations provided to pregnant women. Talk to your provider if you would like to participate in this follow-up service.

Where can I get more information?

- Talk to your GP, Obstetrician or Midwife.
- Contact your local health department.
- Visit the WA HEALTH website at [www.healthywa.wa.gov.au](http://www.healthywa.wa.gov.au)
ANTENATAL VACCINATION CONSENT FORM

Antenatal Vaccination Authorisation and Consent Form

Please Print Neatly in Capital Letters

Last Name

First Name

Date of Birth (eg., 25/08/1980)

Do you identify yourself as Aboriginal or Torres Strait Islander? ☐ Yes ☐ No

This consent form is designed for use with pregnant women consenting to influenza and/or pertussis vaccination at antenatal clinics and community/public health immunisation centres.

Consent for influenza and/or pertussis vaccine during pregnancy

By shading the appropriate circles and signing below:

► I have read and understand the information given to me about influenza and/or pertussis vaccination in pregnancy regarding the anticipated benefits and possible side effects of vaccination. ☐ Yes ☐ No

► I have had an opportunity to have my questions answered. ☐ Yes ☐ No

► I acknowledge that, as a precaution, after the vaccination I will be requested to wait for 15 minutes before leaving the clinic area. ☐ Yes ☐ No

Consent to being contacted by WA Department of Health for quality assurance

As part of our ongoing efforts to continuously monitor vaccine safety, WA Health is requesting your permission to contact you by SMS or telephone to ask about your vaccination experience. If you agree, you will receive an SMS or telephone call several days after vaccination from a Department of Health representative asking whether you experienced any side-effects, including minor ones, following vaccination. You will not be contacted for any other purpose and your information will be kept confidential.

► I acknowledge that by agreeing my healthcare provider will send this form to the Department of Health at the time of my vaccination ☐ Yes ☐ No

► I give my permission to be contacted by telephone or SMS by the WA Department of Health and asked about my vaccination experience in order to monitor vaccine safety. ☐ Yes ☐ No

► I am aware that my decision to participate in this follow-up program is voluntary and will in no way impact the care that I receive. ☐ Yes ☐ No

Signature of person receiving vaccine(s)

Date: d d m m y y y y

Has the person being vaccinated ever had anaphylaxis following previous doses of either of these vaccines? ☐ Yes ☐ No

Has the person being vaccinated ever had anaphylaxis following any component of either of these vaccines? ☐ Yes ☐ No

A “Yes” response warrants further discussion and consideration prior to administration of the vaccine. If you have questions please consult the patient’s primary care physician or relevant specialist. Note that most egg allergic patients can safely receive influenza vaccine, but individuals with a history of anaphylaxis to eating eggs should consult with an allergy specialist prior to being vaccinated.

Week of pregnancy when vaccinated: d d m m y y y y

Estimated date of delivery: d d m m y y y y

Vaccine(s) administered today:

☐ INFLUENZA VACCINE (recommended for women in all trimesters who are pregnant during influenza season):

Vaccine Brand ☐ Vaxigrip ☐ Fluarix ☐ Fluvax ☐ Other

Batch number sticker here

Or write batch number here:

☐ PERTUSSIS VACCINE (recommended for women in 3rd trimester of each pregnancy):

Vaccine Brand ☐ Adacel ☐ Boostrix ☐ Other

Batch number sticker here

Or write batch number here:

Name and designation of person administering vaccine(s) PLEASE PRINT

Vaccine ordering account number:

Signature of person administering vaccine(s)

Date: d d m m y y y y

PLEASE SCAN and EMAIL the completed form to CDCD at antenatal.immunisation@health.wa.gov.au
Antenatal Vaccination Follow-up Forms – 2015

The Western Australia Department of Health is following up pregnant women who receive the seasonal influenza or pertussis vaccine in order to continuously monitor vaccine safety. WA Health is requesting your permission to contact you by SMS or telephone to ask about your vaccination experience.

If you agree to participate in this follow-up, your healthcare provider will fax this form to WA Health at the time of your vaccination. You may receive an SMS or telephone call several days after vaccination from a WA Health representative asking whether you experienced any side-effects, including minor ones, following vaccination. You will not be contacted for any other purpose and your information will be kept confidential.

This follow-up is for quality assurance purposes and is not part of your clinical care. Your decision to participate will not impact the care you receive by your provider. Please consult with your healthcare provider if you have a reaction you think is serious or unexpected. Healthdirect is also available to provide advice on 1800 022 222. For any severe reaction, call an ambulance or go to your closest emergency department.

Your cooperation in assisting with ongoing vaccine safety monitoring is greatly appreciated.

► I give permission for my healthcare provider to fax this form to the Department of Health at the time of my vaccination.

► I agree to be contacted by telephone or SMS by the WA Department of Health and asked about my vaccination experience in order to monitor vaccine safety.

► I am aware that my decision to participate in this follow-up program is voluntary and will in no way impact the care that I receive.

Signature of person receiving vaccine(s)

Date: d d / m m / y y y y

Last Name

First Name

Date of Birth (eg. 13/08/1980) d d / m m / y y y y

Do you identify yourself as Aboriginal or Torres Strait Islander? O Yes O No

Telephone Number (Mobile preferred): ________________________________

To be completed by person administering vaccine

Week of pregnancy when vaccinated: d d d d weeks OR Estimated date of delivery: d d / m m / y y y y

Vaccine(s) administered today:

O INFLUENZA VACCINE (recommended for women in all trimesters who are pregnant during influenza season):

Vaccine Brand O Vaxigrip O Fluarix O Fluvax O Other

Batch number sticker here

Or write batch number here: ________________________________

O PERTUSSIS VACCINE (recommended for women in 3rd trimester of each pregnancy):

Vaccine Brand O Adacel O Boostrix O Other

Batch number sticker here

Or write batch number here: ________________________________

Clinic stamp

Or write clinic name here:

Practice number (used for ordering vaccines):

Signature of person administering vaccine(s)

Date: d d / m m / y y y y

PLEASE FAX the completed form to the Communicable Disease Control Directorate at (08) 9388 4877