Influenza vaccination during pregnancy (and in women planning pregnancy)

Objectives: To provide advice on influenza and vaccination during pregnancy and in women planning pregnancy.

Options: Immunisation against influenza versus no immunisation.

Outcomes: To minimise the incidence of influenza infection in pregnant women, in women planning pregnancy and in babies up to 6 months of age.

Target audience: All health practitioners providing maternity care and patients.

Validation: This statement is in line with the recommendations in the 10th edition of the Australian Immunisation Handbook.¹

Funding: The development and review of this statement was funded by RANZCOG.

Background: This statement was originally developed in November 2011 and it was reviewed in November 2013 following publication of the 10th edition of the Australian Immunisation Handbook.¹

Disclaimer: This College Statement is intended to provide general advice to practitioners. The statement should never be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of each patient. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The statement has been prepared having regard to general circumstances.

First endorsed by RANZCOG: November 2011
Current: November 2013
Review due: November 2016

This statement has been developed and reviewed by the Women’s Health Committee and approved by the RANZCOG Board and Council.

A list of Women’s Health Committee Members can be found in Appendix A.

Disclosure statements have been received from all members of this committee.
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1. **Patient summary**

Pregnant women are at high risk of severe consequences of influenza infection. This is because there are a number of changes that occur to a woman’s body during pregnancy which may put pregnant women at higher risk of complications from the flu (e.g. changes to lung function, increased cardiac output, increased oxygen consumption, and changes to the immune response).

The best way to protect pregnant women against flu is by vaccinating against it. Vaccination needs to be given each year because the viruses are always changing. Vaccinating against flu during pregnancy provides protection for the mother and the newborn baby for the first six months after birth.

The influenza vaccine is safe for pregnant women in all trimesters, with no unusual patterns in pregnancy or fetal outcomes being observed in vaccine adverse events reports.

2. **Summary of recommendations**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Grade and reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Influenza vaccination</strong></td>
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</tr>
<tr>
<td><strong>Recommendation 1</strong></td>
<td></td>
</tr>
<tr>
<td>Influenza vaccination is recommended for all pregnant women regardless of gestation, and in women planning pregnancy.</td>
<td>Consensus-based recommendation 1</td>
</tr>
<tr>
<td><strong>Good Practice Notes</strong></td>
<td></td>
</tr>
<tr>
<td>Free influenza vaccine is available to all pregnant women in <strong>Australia</strong> and <strong>New Zealand</strong>.</td>
<td></td>
</tr>
<tr>
<td>To receive the influenza vaccination, pregnant women are advised to visit their local doctor or immunisation provider. It is important to note that the vaccine is free; however a consultation fee may apply.</td>
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<tr>
<td><strong>Recommendation 2</strong></td>
<td></td>
</tr>
<tr>
<td>Vaccination early in the season and regardless of gestational age is optimal, but unvaccinated pregnant women should be immunised at any time during influenza season as long as the vaccine supply lasts.</td>
<td>Consensus-based recommendation</td>
</tr>
<tr>
<td><strong>Recommendation 3</strong></td>
<td></td>
</tr>
<tr>
<td>The Royal Australian and New Zealand College of Obstetricians and Gynaecologists strongly endorse routine vaccination of obstetric and midwifery staff, both to protect these individuals as well as their families, close contacts and patients.</td>
<td>Consensus-based recommendation</td>
</tr>
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</table>
3. Introduction

Influenza is a very serious and potentially life-threatening illness, caused by the influenza virus. Major outbreaks associated with severe disease are usually caused influenza virus types A and B. While influenza B is a human disease, subtypes of influenza A, characterized by differing haemagglutinin (H) and neuraminidase (N) antigens, infect many species. The H and N antigens frequently change their protein structure, leading to the development of new strains of influenza A virus that may infect humans and cause serious disease. For this reason, new vaccination preparations must be developed for each pandemic season.

Although most healthy people will suffer a serious but self-limited illness lasting one to two weeks, some groups are particularly vulnerable to significant disease and potentially death. Pregnant women are more likely to become seriously ill and to die than the general population. This vulnerability probably relates to changes in maternal physiology, including changes to the respiratory and cardiovascular system with reduced lung capacity and changes in the immune system.

Influenza vaccination during pregnancy should be routine: safety is well established\(^2\text{-}^9\) and both maternal and infant benefit is now proven with only 5 vaccination doses estimated to prevent one case of serious maternal or infant respiratory illness.\(^9\)
4. Evidence Summary and Recommendations

4.1 What are the risks associated with influenza infection during pregnancy?
Preventing influenza during pregnancy is an essential part of antenatal care because pregnant women are at an increased risk of serious illness due to influenza. Excess morbidity and mortality in pregnant women infected with influenza compared with non-pregnant women of similar age who are infected with influenza has been noted during pandemics as long ago as 1918 but drew public and professional attention most recently during 2009.

The risk to the mother of complications from influenza increases in the later stages of pregnancy. Infection in the third trimester of pregnancy appears to be the most dangerous for the pregnant woman.

4.2 Should pregnant women or those planning pregnancy be vaccinated against influenza?
The most effective strategy for preventing influenza in pregnant women is annual immunisation. Influenza vaccination is estimated to prevent 1 to 2 hospitalisations per 1000 women vaccinated during the second or third trimester.

The Australian Government Department of Health and Ageing strongly recommends vaccination during the influenza season for pregnant women and women planning pregnancy. (see Chapter 4.7).

The New Zealand Ministry of Health strongly recommends seasonal influenza vaccination for all women who will be pregnant during the influenza season (which is usually between May to October).

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists strongly endorse routine influenza vaccination of pregnant women and women planning pregnancy.

In Australia and New Zealand, the flu season is considered to be between May to October, usually peaking by the end of August.

The influenza vaccine is available for free to all pregnant women in Australia and New Zealand.
**Recommendation 1**

| Grade and reference | Influenza vaccination is recommended for all pregnant women regardless of gestation, and for women planning pregnancy. | Consensus-based recommendation 1 |

**Good Practice Notes**

| Grade | Free influenza vaccine is available to all pregnant women in Australia and New Zealand |

To receive the influenza vaccination, pregnant women are advised to visit their local doctor or immunisation provider. It is important to note that the vaccine is free; however a consultation fee may apply.


**4.3 What is the optimal timing of influenza vaccination in pregnant women or those planning pregnancy?**

Inactivated influenza vaccine is usually available from February each year in the Southern Hemisphere. Live attenuated influenza vaccination has not been licensed in Australia.¹

Vaccination early in the season and regardless of gestational age is optimal, but unvaccinated pregnant women should be immunised at any time during influenza season as long as the vaccine supply lasts.

In Australia and New Zealand, the flu season is considered to be between May to October, usually peaking by the end of August.¹⁹

Whilst it is recommended that all pregnant women should be immunised as early as possible in pregnancy,²⁰ the precise timing of vaccination will depend on the time of year, vaccine availability, influenza seasonality, gestation of pregnancy and the likely duration of immunity.

The vaccine should be administered annually to maintain immunity and to provide protection against new strains.

**Recommendation 2**

| Grade | Vaccination early in the season and regardless of gestational age is optimal, but unvaccinated pregnant women should be immunised at any time during influenza season as long as the vaccine supply lasts. | Consensus-based recommendation |

**4.4 Are there any adverse consequences to vaccinating pregnant women or those planning pregnancy against influenza?**

No study to date has shown an adverse consequence of inactivated influenza vaccine in pregnant women or their offspring.²⁻⁵, ⁷⁻⁹ ¹⁸, ²¹
Influenza vaccination is safe at any stage of pregnancy and there is no preference for any specific type of influenza vaccine in pregnancy; all are considered acceptable for use in pregnant women.

The only absolute contraindications to influenza vaccines are:

- anaphylaxis following a previous dose of any influenza vaccine; or
- anaphylaxis following any vaccine component.

See section 4.7.10 of the 10th edition Australian Immunisation Handbook for precautions for persons with a known egg allergy.1

4.5 Does influenza vaccination during pregnancy provide protection for infants?
Active placental transfer of maternal antibodies makes influenza vaccine during pregnancy a highly effective measure to protect infants from influenza during the first 6 months of life.9, 14, 22, 23 Most evidence around infant protection is from studies of maternal influenza vaccination in the second or third trimester. 2-5, 9, 14-18, 22 No study to date has shown an adverse consequence of inactivated influenza vaccine in pregnant women or their offspring.6, 18, 24

4.6 How long after vaccination can protection be expected?
Some maternal benefit is might accrue as early as 2 weeks after vaccination with research in pregnant women demonstrating seroconversion by 4 to 6 weeks after vaccination.5

4.7 Should obstetric and midwifery staff be vaccinated against influenza?

<table>
<thead>
<tr>
<th>Recommendation 3</th>
<th>Grade and reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Royal Australian and New Zealand College of Obstetricians and Gynaecologists strongly endorse routine vaccination of obstetric and midwifery staff, both to protect these individuals as well as their families, closes contacts and patients.</td>
<td>Consensus-based recommendation</td>
</tr>
</tbody>
</table>
5. Links to other College statements
(C-Gen 15) Evidence-based Medicine, Obstetrics and Gynaecology
medicine-obstetrics-and-gynaecology.html?Itemid=341

6. Patient information
1. NZ patient information - Pregnant Women, Influenza and Influenza Vaccination and
   Frequently Asked Questions

2. Australian Department of Health - Influenza (Flu)

7. References
   2013.
2. American College of Obstetricians and Gynecologists Committee Opinion No. 468. Influenza
3. Black SB, Shinefield HR, France EK, Fireman BH, Platt ST, Shay D, et al. Effectiveness of
   influenza vaccine during pregnancy in preventing hospitalizations and outpatient visits for
   infection in the second and third trimesters of pregnancy: a clinical and seroepidemiological
   pregnant women following administration of trivalent inactivated influenza vaccine and live
7. Sheffield JS, Greer LG, Rogers VL, Roberts SW, Lylte H, McIntire DD, et al. Effect of
15. Englund JA, Mbawuike IN, Hammill H, Holleman MC, Baxter BD, Glezen WP. Maternal
    immunization with influenza or tetanus toxoid vaccine for passive antibody protection in young
    maternal influenza vaccination during pregnancy on the incidence of acute respiratory illness
17. MacDonald NE, Riley LE, Steinhoff MC. Influenza immunization in pregnancy. Obstet

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Appendices

Appendix A Women’s Health Committee Membership

<table>
<thead>
<tr>
<th>Name</th>
<th>Position on Committee</th>
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<tbody>
<tr>
<td>Associate Professor Stephen Robson</td>
<td>Chair</td>
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<tr>
<td>Professor Susan Walker</td>
<td>Deputy Chair - Obstetrics</td>
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<tr>
<td>Dr Gino Pecoraro</td>
<td>Deputy Chair - Gynaecology</td>
</tr>
<tr>
<td>Professor Yee Leung</td>
<td>Member</td>
</tr>
<tr>
<td>Associate Professor Anuschirawan Yazdani</td>
<td>Member</td>
</tr>
<tr>
<td>Dr Simon Craig</td>
<td>Member</td>
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<tr>
<td>Associate Professor Paul Duggan</td>
<td>Member</td>
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<tr>
<td>Dr Vijay Roach</td>
<td>Member</td>
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<tr>
<td>Dr Stephen Lyons</td>
<td>Member</td>
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<tr>
<td>Dr Ian Page</td>
<td>Member</td>
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<td>Dr Donald Clark</td>
<td>Member</td>
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<td>Dr Amber Moore</td>
<td>Member</td>
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<td>Dr Martin Ritossa</td>
<td>Member</td>
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<tr>
<td>Dr Benjamin Bopp</td>
<td>Member</td>
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<tr>
<td>Dr James Harvey</td>
<td>Member</td>
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<tr>
<td>Dr John Tait</td>
<td>Member</td>
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<tr>
<td>Dr Anthony Frumar</td>
<td>Member</td>
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<tr>
<td>Dr Kirsten Black</td>
<td>Member</td>
</tr>
<tr>
<td>Dr Jacqueline Boyle</td>
<td>Chair of IWHC</td>
</tr>
<tr>
<td>Dr Louise Sterling</td>
<td>GPOAC representative</td>
</tr>
<tr>
<td>Ms Catherine Whitby</td>
<td>Council Consumer representative</td>
</tr>
<tr>
<td>Ms Susan Hughes</td>
<td>Consumer representative</td>
</tr>
<tr>
<td>Ms Sherryn Elworthy</td>
<td>Midwifery representative</td>
</tr>
<tr>
<td>Dr Kathryn van Harselaar</td>
<td>Trainee representative</td>
</tr>
<tr>
<td>Dr Agnes Wilson</td>
<td>RANZCOG guideline developer</td>
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Appendix B Overview of the development and review process for this statement

i. Steps in developing and updating this statement

This statement was originally developed in November 2011 and was reviewed in July 2013. The Women’s Health Committee carried out the following steps in reviewing this statement:

- Declarations of interest were sought from all members prior to reviewing this statement.

- The November 2011 statement was compared with the recommendations in the 10th edition of the Australian Immunisation Handbook\(^1\) and updates were made where required.

- Recommendations were graded as set out below in Appendix B part iii).

- The updated statement was circulated out-of-session to the Women’s Health Committee for comment and approval.

ii. Declaration of interest process and management

Declaring interests is essential in order to prevent any potential conflict between the private interests of members, and their duties as part of the Women’s Health Committee.

A declaration of interest form specific to guidelines and statements was developed by RANZCOG and approved by the RANZCOG Board in September 2012. The Women’s Health Committee
members were required to declare their relevant interests in writing on this form prior to participating in the review of this statement.

Members were required to update their information as soon as they become aware of any changes to their interests and there was also a standing agenda item at each meeting where declarations of interest were called for and recorded as part of the meeting minutes.

There were no significant real or perceived conflicts of interest that required management during the process of updating this statement.

iii. Grading of recommendations

Each recommendation in this College statement is given an overall grade as per the table below, based on the National Health and Medical Research Council (NHMRC) Levels of Evidence and Grades of Recommendations for Developers of Guidelines. Where no robust evidence was available but there was sufficient consensus within the Women’s Health Committee, consensus-based recommendations were developed or existing ones updated and are identifiable as such. Consensus-based recommendations were agreed to by the entire committee. Good Practice Notes are highlighted throughout and provide practical guidance to facilitate implementation. These were also developed through consensus of the entire committee.

<table>
<thead>
<tr>
<th>Recommendation category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence-based</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>Body of evidence can be trusted to guide practice</td>
</tr>
<tr>
<td>B</td>
<td>Body of evidence can be trusted to guide practice in most situations</td>
</tr>
<tr>
<td>C</td>
<td>Body of evidence provides some support for recommendation(s) but care should be taken in its application</td>
</tr>
<tr>
<td>D</td>
<td>The body of evidence is weak and the recommendation must be applied with caution</td>
</tr>
<tr>
<td>Consensus-based</td>
<td>Recommendation based on clinical opinion and expertise as insufficient evidence available</td>
</tr>
<tr>
<td>Good Practice Note</td>
<td>Practical advice and information based on clinical opinion and expertise</td>
</tr>
</tbody>
</table>
Appendix C Full Disclaimer

This information is intended to provide general advice to practitioners, and should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient.

This information has been prepared having regard to general circumstances. It is the responsibility of each practitioner to have regard to the particular circumstances of each case. Clinical management should be responsive to the needs of the individual patient and the particular circumstances of each case.

This information has been prepared having regard to the information available at the time of its preparation, and each practitioner should have regard to relevant information, research or material which may have been published or become available subsequently.

Whilst the College endeavours to ensure that information is accurate and current at the time of preparation, it takes no responsibility for matters arising from changed circumstances or information or material that may have become subsequently available.