



Australian Government

Department of Health and Ageing

CHIEF MEDICAL OFFICER

Dear Colleagues,

I am writing to update you on the severe impact that pandemic (H1N1) 2009 has had upon pregnant and postpartum women and to advise you to encourage your patients who are pregnant, or who are planning a pregnancy, that they be vaccinated against pandemic (H1N1) 2009. I also want to tell you about a mechanism we have put in place through the Therapeutic Goods Administration and CSL Limited to monitor pregnant women who receive the pandemic vaccine.

Our experience in Australia has been that the first wave of the pandemic lasted around 18 weeks. It was a moderate illness overall with a hospitalisation rate above 1% (around 4,900 admissions or 22/100,000 population to 28th October), 13% of these were admitted to ICU with 186 deaths confirmed to be associated with the virus. This activity stretched our health system, particularly our intensive care services peaking in late July.

Experience from history and from other countries with this virus shows that, unlike seasonal influenza, pandemic influenza is not just a winter infection. In the next few months a number of possible scenarios could occur. As has happened over the Northern Hemisphere summer, we may continue to have ongoing outbreaks of various sizes and spread in our communities. We may face a major out-of-season influenza outbreak due to importation of the virus back into Australia from infected travellers. Thus a second wave may occur at any time or the virus may mutate and become more virulent, causing another large outbreak now or next winter. Vaccination now will protect the community against all the scenarios possible with this unpredictable pandemic virus.

Whilst the pandemic influenza has been moderate overall, some population groups have experienced severe disease. One of these groups is pregnant women and their infants. Let me summarise some of our Australian data for the impact of the pandemic on pregnant women:

- 16% of ICU cases have been pregnant women;
- 32% (62/191) of women aged 15 - 44 years admitted to ICU for pandemic H1N1 were pregnant. Of the women aged 20 - 29 years, 47 % were pregnant;

- Of all pregnant women admitted to ICU, 56% did not have any co-morbidities such as asthma or diabetes;
- Pregnant women stayed an average of 15 days in hospital (Range 1 – 63 days).
- Three pregnant women have died.

These Australian data are consistent with what is known about the previous impacts of pandemic influenza and with data that have emerged from overseas. We do not have equivalent ICU data for pregnant women for seasonal influenza for comparison but our information from the Australian and New Zealand Intensive Care Society is that the impact of pandemic (H1N1) 2009 on Australian pregnant women has been much more severe than that of seasonal influenza.

The Australian Technical Advisory Group on Immunisation (ATAGI) recommended in the 9th Edition of The Australian Immunisation Handbook 2008 that pregnant women have trivalent inactivated influenza (TIV) against seasonal influenza because of the risks that seasonal influenza poses to the woman and her foetus. Likewise ATAGI has considered that pregnant women should be in the highest priority group to have the monovalent vaccine against pandemic H1N1 2009, Panvax™.

The monovalent CSL Ltd vaccine Panvax™ is made using the same techniques that have been used to make seasonal vaccine for over 40 years. It has been registered by the Therapeutic Goods Administration (TGA) and meets all the relevant standards for safety and efficacy. Unlike TIV it does contain thiomersal, but the risk posed by the presence of a small quantity of this preservative has been assessed by expert groups who consider this to be safe. ATAGI have conducted a detailed analysis of the use of influenza vaccines containing thiomersal and advise that the pandemic vaccine is safe for infants, children, adolescents and adults including pregnant and breastfeeding women. The ATAGI advice is on the health emergency website at www.healthemergency.gov.au.

The consistent recommendations by ATAGI, the Institute of Medicine (IOM), the Centres for Disease Control and Prevention (CDC) and the World Health Organisation (WHO) are that the benefits of vaccination against pandemic (H1N1) 2009 far outweigh any theoretical risks associated with the vaccine. In addition, there is increasing evidence that influenza vaccination of a pregnant woman will provide the neonate with some protection against influenza for the first six months of life. (Vaccination of infants younger than six months is not currently recommended by any specialist body.) This intervention may be life saving for both mother and baby.

Finally, I want to advise you that as part of the safety monitoring activities being undertaken by CSL Limited for Panvax™, CSL Limited is developing a voluntary pregnancy register. CSL will follow up any report of a pregnant woman receiving the vaccine *that is notified to them* to the outcome of the pregnancy. This will provide important safety information on influenza vaccines as well as the Panvax™ vaccine specifically.

I encourage you both to support your patients to have this vaccine and would suggest also that you seek the consent of your patient to advise CSL on 1800 024 204 that your patient has received the vaccine.

Yours sincerely

A handwritten signature in black ink, appearing to read "Jim Bishop". The signature is written in a cursive style with a large initial "J" and "B".

Professor Jim Bishop AO
MD MMed MBBS FRACP FRCPA

2nd November 2009