

To: All General Practitioners  
All Practice Nurses Working in Practice

Copy: Community Pharmacists

**Gateway Reference:** 12902

2 November 2009

Dear Colleague

**Swine flu vaccination programme: Information to support the vaccination of pregnant women**

Swine flu vaccine is being distributed to general practices over the next few weeks. In the Chief Medical Officer's letter of 15 October, (available at [http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH\\_107169](http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_107169)), he set out information for clinicians about the delivery of the swine flu vaccination programme. This communication contains additional information about the vaccination of pregnant women.

You will, I know, appreciate that it is critical that clinicians are well placed to offer appropriate reassurance to pregnant women, their families and friends. We recognise that a few recent media stories have caused anxiety and apprehension in some pregnant women about receiving the swine flu vaccine.

Both the vaccines we have purchased have been licensed for use in pregnant women. Licensed vaccines, including influenza vaccines, are held to a very high standard of safety and the vaccines would not be licensed if they were considered unsafe.

There is good and increasing evidence that pregnant women are at higher risk of the serious consequences of swine flu. This evidence suggests that pregnant women are more likely to develop serious complications from swine flu and the World Health Organization has stated that seven to ten percent of all hospitalised patients with swine flu are pregnant women in their second or third trimester. This emphasises the benefits of an effective and comprehensive vaccination programme for this at risk group.

We have, therefore, developed a comprehensive Question & Answer sheet that we hope will support your consultations with pregnant women who may have questions and concerns. The information also covers the clinical evidence and rationale for the JCVI advice to prioritise pregnant women for vaccination.

In addition, the Department of Health website has a specific section providing resources and guidance for pregnant women, parents and health professionals on swine flu. This includes the latest guidance on antiviral use in pregnant women and the Chief Medical Officer's advice to pregnant women. Guidance on the clinical management of pregnant women with H1N1 infection has been published and is available at:  
<http://www.dh.gov.uk/en/Publichealth/Flu/Swineflu/InformationandGuidance/Pregnancy/index.htm>

The Green Book (Immunisation against infectious disease) has also now been updated to reflect the latest advice that relates to vaccination during pregnancy:  
[http://www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/DH\\_4097254](http://www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/DH_4097254)

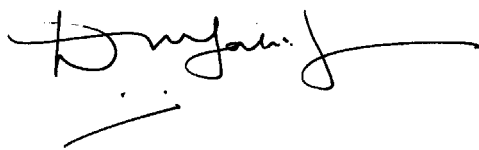
To support the vaccination programme, the Department of Health has produced a patient leaflet suitable for all recipients of the new vaccine that could be included with any invitation letters sent out, posters that can be used to advertise local clinics and raise awareness and vaccination appointment/record cards.

These can be ordered through [www.orderline.dh.gov.uk](http://www.orderline.dh.gov.uk) quoting:

- Swine flu vaccination leaflet 297563
- Swine flu vaccination information poster 299247
- Swine flu vaccination empty belly poster 299248
- Swine flu vaccination appointment cards 299249

If you have any further queries about the vaccination programme, please direct your enquiries to [Mbswinefluvaccination@dh.gsi.gov.uk](mailto:Mbswinefluvaccination@dh.gsi.gov.uk)

Yours sincerely



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## **Q&A**

### **Q. Why are pregnant women in one of the priority at-risk groups?**

**A.** Epidemiological evidence from North America, Australia and Europe shows that pregnant women are at increased risk of severe disease and influenza-related hospital admission. This increased risk has also been observed in the UK. The risk increases with gestational age with pregnant women in the third trimester particularly at risk. (WHO 2009, Jain *et al.*, 2009, Jamieson *et al.*, 2009).

The World Health Organization has stated that 7% to 10% of all hospitalised patients are pregnant women in their second or third trimester of pregnancy. Pregnant women are ten times more likely to need care in an intensive care unit when compared with the general population. (WHO, 2009).

Complications in pregnant women, based on information in relation to seasonal flu, may include pneumonia and cardio-respiratory complications (Kort BA *et al.*, 1986; Neuzil KM *et al.*, 1998).

### **Q. Is the vaccine safe for pregnant women?**

**A.** Both vaccines have been licensed for use in pregnant women. Licensed vaccines, including influenza vaccines, are held to a very high standard of safety and the vaccines would not be licensed if they were considered unsafe.

In licensing the current swine flu vaccines for use in pregnancy, the European regulators gave careful consideration to the severe burden of illness caused by swine flu in pregnant women. They also considered the safety record of seasonal influenza vaccines and the nature of the adjuvants that were incorporated in the pandemic vaccines. There is extensive safety experience from seasonal influenza vaccination in all trimesters of pregnancy, since such vaccination has been recommended for several years in many countries. In the UK, vaccination against seasonal influenza is also recommended for pregnant women who are in the clinical at-risk groups, regardless of the stage of pregnancy.

No safety concerns have been raised after vaccination of millions of pregnant women with seasonal flu vaccines. There is no indication from reproductive toxicity studies that inclusion of adjuvants is associated with any risks in pregnancy.

### **Q. What was the most recent advice from JCVI on vaccinating pregnant women?**

**A.** JCVI recommended that pregnant women should be given Pandemrix as this vaccine appears to give adequate levels of antibodies after a single dose thereby conferring protection more rapidly than would be afforded by Celvapan, which requires a two-dose schedule given three weeks apart.

**Q. Why is thiomersal present in the vaccine and is there any risk from it?**

**A.** Pandemrix is supplied in multi-dose vials and contains five micrograms of thiomersal as a preservative. This is added to prevent bacterial contamination occurring during the preparation and subsequent storage and use of the vaccine.

There is no evidence of risk from thiomersal in vaccines, including for children, pregnant women and their offspring. In 2003, the Committee on Safety of Medicines (CSM) concluded that the balance of benefits and risks of thiomersal-containing vaccines remains overwhelmingly positive (CSM, 2003). In 2004, the European Medicines Agency (EMA) also concluded that studies show no association between vaccination with thiomersal-containing vaccines and specific neurodevelopmental disorders (EMA, 2004). A more recent study has also shown no association between neuropsychological functioning at the age of seven to ten years and exposure to mercury during the prenatal period, the neonatal period and the first seven months of life (Thompson *et al.*, 2007). Rates of autism in the US continued to rise after thiomersal was removed from childhood vaccines with no change in the rate of rise.

**Q. What is an adjuvant?**

**A.** An adjuvant is a compound that can be added to a vaccine to enhance the immune response to the vaccine. The use of an adjuvant can also reduce the amount of antigen that is needed to produce a satisfactory immune response.

Pandemrix contains an adjuvant (AS03) that is composed of squalene, DL- $\alpha$ -tocopherol (i.e. Vitamin E) and polysorbate 80.

Squalene is a naturally occurring substance that is manufactured in the liver of every human body and circulates in our bloodstream. Squalene used in vaccines is purified from fish oil. Squalene is also present in the adjuvant (MF59) of a seasonal flu vaccine called FluAd that has been given to tens of millions of people since 1997. There have been no safety concerns with Fluad or its MF59 adjuvant.

Polysorbate 80 is an emulsifying agent widely used in cosmetics, food products, and pharmaceuticals including injections.

The World Health Organisation has recommended that any licensed vaccine can be used in pregnant women (WHO, 2009).

**Q. There have been concerns about the use of adjuvanted vaccines in pregnant women; what is the Department of Health's recommendation?**

**A.** The European Medicines Agency has licensed Pandemrix, which contains an adjuvant, for use in pregnancy. This followed a thorough evaluation of the safety of the vaccine, and its adjuvant, as well as the severe disease caused by swine flu in pregnant women. In early June, WHO reviewed the safety of adjuvants and no significant safety concerns were identified.

JCVI has advised that pregnant women receive the adjuvanted vaccine Pandemrix as this vaccine appears to give adequate levels of antibodies after a single dose thereby conferring protection more rapidly than would be afforded by Celvapan. As pregnant women are at increased risk of severe disease and hospitalisation, it is vital that they are protected as soon as possible from swine flu infection.

**Further information on vaccines given in pregnancy:**

Seasonal flu vaccines are already licensed to be given routinely to pregnant women and indeed our policy for seasonal flu vaccination says that if you are in a risk group and pregnant, you should have seasonal flu vaccine. In the US, seasonal flu vaccine is recommended for all pregnant women.

Where swine flu is concerned, we can see good evidence that pregnant women are indeed at higher risk of the serious consequences of infection and for this reason, all authorities that have produced priority lists, including the World Health Organization (WHO), have included pregnant women.

No vaccines are routinely tested in pregnant women. Vaccines are given to pregnant women, when it is clinically necessary. For example polio, tetanus and indeed seasonal flu vaccines are given where indicated.

This is a balance of benefit and risk. We have no reason to believe there is a risk of harm from giving the swine flu vaccines in pregnancy and we can see clear evidence of potential harm for both the mother and baby from contracting flu in pregnancy.

The World Health Organisation has recommended that any licensed vaccine can be used in pregnant women (WHO, 2009).

**Q. Have the vaccines been tested on pregnant women?**

**A.** Women who are already pregnant are generally not enrolled into clinical trials. The safety of giving a particular vaccine to pregnant women is assessed from what is already known about the ingredients in the vaccine and the results of testing in reproductive toxicity studies. However, non-pregnant women who are enrolled into vaccine clinical trials sometimes become pregnant shortly after vaccination or are given vaccine before they know they are pregnant. These women are followed up and the outcome of the pregnancy is documented. The information gained adds to the assessment of any possible risks. Of the women who became pregnant during the clinical trials with H5N1 vaccine using the same adjuvant, there is no evidence of any specific risks to the mother or foetus due to the vaccine

Clinical trials of the pandemic influenza vaccines provided good results in women of child-bearing age and based on experience from other influenza vaccines it is assumed that the antibody response is similar in pregnant women and non-pregnant women.

Reproductive toxicity studies, and experience from other types of vaccines, both non-adjuvanted and adjuvanted, do not raise concerns with respect to their use during pregnancy.

**Q. Can pregnant women be offered the vaccine at any stage of pregnancy?**

**A.** Yes. The vaccines are licensed for use at any stage of pregnancy.

**Q. Where can I find more information on the swine flu vaccine in relation to these issues and others?**

**A.** The new Green Book chapter (Pandemic influenza A(H1N1)v 2009 (swine flu)) can be found at:

[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_107361.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_107361.pdf)

Further information materials on the vaccination programme can be found at:

<http://www.dh.gov.uk/swinefluvaccinertools>

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