

Addressing The Myths About The H1N1 Pandemic Influenza Vaccine

The Children's Hospital at Westmead

Thursday, 1 October 2009

VACCINATION PROGRAM

MYTH

The vaccination campaign has been rushed through and therefore could pose health risks for Australians

FACT

- Panvax® H1N1 vaccine meets the rigorous requirements for registration by Australia's Therapeutic Goods Administration
- Pandemic vaccines are made using the same manufacturing process as for seasonal flu vaccines which have an extensive body of safety data
- Preliminary results from a study in healthy adults showed that the vaccine was generally well tolerated with a safety and tolerability profile consistent with that seen with seasonal flu vaccines¹
- We know that 179 Australians have already died of swine flu and 4,788 have been hospitalised²

1. Greenberg M et al 2009 NEJM p361

2. Available at: www.healthemergency.gov.au

SEVERITY OF SWINE FLU

MYTH

Swine flu is a mild disease so you are better off becoming immune by catching it rather than being vaccinated

FACT

- While pandemic (H1N1) 2009 influenza is mild in most cases it has been severe in some people. In the five-month period from May to September 2009, there have been:
 - 4500 hospitalisations and hundreds of intensive care unit admissions
 - 179 deaths

GBS (Guillain-Barré Syndrome)

MYTH

Swine flu vaccines have caused paralysis (Guillain-Barré Syndrome) in the past and are likely to do so again

FACT

- The vaccine and the virus strain in the 1976 outbreak that some have associated with GBS are different from those today¹
- Studies on seasonal influenza vaccines subsequent to the 1976 vaccine have shown no or very minimal increased risk of GBS²
- There is a far greater risk of GBS following an influenza-like illness than vaccination²
- Approximately 1 in 100,000 adults develop GBS every year in the general population (regardless of whether they have received the vaccine or not)³

1. Evans et al. J Infect Dis. 2009 Aug 1;200(3):321-8

2. Stowe et al 2009 Am J Epidemiol Vol 119 Issue 6 pg 841-879

3. ACIP 2008 MMWR Aug 8 2008 Vol 57 No RR-7

MULTI-DOSE VIALS

MYTH

The use of multi-dose vials (MDV) to store and distribute the vaccine poses a public health risk

FACT

- This presentation allows for the most rapid response in a National emergency situation, facilitating the distribution and supply of a large number of doses of vaccine
- The US uses MDV for its normal seasonal vaccine and has done so safely for the past 30 years. Just about all countries in the world that will have pandemic vaccination programs will use MDV to ensure rapid delivery of vaccine to their populations
- The risk of transmitting infectious diseases via MDV is very low if strict infection control procedures are followed
 - Guidelines for use of the MDV have been developed by ATAGI (Australian Technical Advisory Group on Immunisation) and will be available from the RACGP website, along with DVD demonstration for training purposes

CONTENTS

MYTH

The vaccine contains mercury, which is a toxic substance usually banned in vaccines

FACT

- The vaccine contains a small amount of thiomersal, a mercury-based preservative that has been used to ensure sterility in vaccines around the world for 60 years
- Thiomersal has been used for decades in the US in MDV of some vaccines, and is still used today
- The WHO Global Advisory Committee on Vaccine Safety (GACSV) reviews the safety of thiomersal-containing vaccines on a regular basis and has concluded that there is currently no evidence of mercury toxicity in infants, children, adolescents or adults (including pregnant women) exposed to thiomersal in vaccines¹
- Some foods also contain trace amounts of mercury

1. ATAGI advice regarding the use of influenza vaccines containing thiomersal <http://www.racgp.org.au/h1n1>

PREGNANT WOMEN

MYTH

The vaccine has not been tested in pregnant women and is therefore unsafe to use in pregnancy

FACT

- Vaccination has the potential to protect a woman and her baby from the H1N1 virus, based on the experience with seasonal vaccines¹
- Pregnant women are at higher risk of morbidity and mortality from complications of pandemic flu compared with the general population¹
- The WHO, ACIP and NHMRC all recommend influenza vaccination in pregnancy¹

1. Mak et al. Lancet Infect Dis. 2008 Jan;8(1):44-52

CHILDREN

MYTH

Flu vaccines are unsafe to use in children, particularly at the 'adult' doses used in the clinical trials

FACT

- Children (aged 6 months to 9 years) will not be included in the first round of vaccinations as pediatric clinical trials are ongoing and interim trial data are not expected until mid-late October
- Dosage requirements will be established once the clinical trial data are available
- Seasonal influenza vaccines are recommended and have been shown to be safe in children (NHMRC Handbook, 2009)

CLINICAL TRIALS

MYTH

The clinical trials are not yet complete so it is far too early to start the program when the vaccine hasn't been properly tested

FACT

- The H1N1 vaccine clinical trial data have been assessed by the Australian and US regulatory bodies and the vaccine has been approved for use
- Apart from the influenza virus strain used, the formulation of Panvax[®] H1N1 vaccine is the same as the CSL seasonal influenza vaccine, except that a small amount of the preservative thiomersal has been added to the multi-dose vials
- CSL will continue to work with the Australian Government to monitor the safety of the vaccine and investigate reports of adverse events after vaccination

EGG ALLERGIES

MYTH

People with egg allergies should not use the CSL flu vaccine

FACT

- Most Australians with egg allergies have a mild allergic reaction to egg¹ and can use the vaccine under medical supervision
- Only a small proportion of Australians have an anaphylactic response to egg proteins². Vaccination is not recommended in these people

1. James JN, Zeiger MS, Lester MR 1998 J. Pediat 133 (5) 624-628

2. Heine RG, Laske N, Hill DJ (2006). *Current allergy and asthma reports* 6: 145-152.

INSURANCE

MYTH

Doctors and health professionals will not be indemnified if they use the vaccine

FACT

- All medical indemnity insurer organisations (MDA National, Medical Indemnity Protection Society, Avant, Invivo and MIGA) have confirmed that they will insure members involved in the H1N1 vaccination program¹

1. Available at: www.healthemergency.gov.au

DEDICATED WEBSITE FOR AUSTRALIANS

The screenshot shows a Windows Internet Explorer browser window displaying the H1N1 Vax Assist website. The browser's address bar shows the URL: <http://www.h1n1vax.com.au/s1/cs/auvx/1247066989802/content/1247066992399/home.htm>. The website features the CSL logo in the top left corner and a search bar with a "SEARCH" button. Below the logo, the text "H1N1 Vax Assist" is displayed. A navigation menu on the left includes links for "Background on CSL's Pandemic H1N1 Vaccine", "About Panvax®H1N1 vaccine", and "Vaccination Program". A central image shows a healthcare professional administering a vaccine to a child. A text box overlaid on the image reads: "Welcome to H1N1 Vax assist. This site contains information for consumers on CSL's Pandemic (H1N1) vaccine." To the right of the image, there is a "Sitemap" link and a "More information? Visit the Government website" button. The CSL logo is also present in the bottom right corner of the website, along with the copyright notice: "© 2009 CSL Limited Terms of Use".

www.h1n1vax.com.au

CSL™

Questions?

