



Fighting THE FLU

Ensuring vaccine safety is a high priority. Influenza vaccines have been used for more than 60 years and have an established record of safety in all age groups. Before being used, vaccines must pass many safety tests, writes **DR KEVIN KELLEHER** and **DR DARINA O'FLANAGAN**.

Pandemic (H1N1) 2009, a new form of flu that has spread throughout the world since April 2009, was formerly known as Influenza A (H1N1) or Swine Flu. While there is evidence that some elderly people have some immunity most people under 65 years have no immunity and are therefore at risk of catching it. This includes healthy adults as well as young children, those with pre-existing medical conditions and most older people.

Since spring 2009, over 254,206 people worldwide have had laboratory confirmed pandemic (H1N1) 2009, with at least 3,281 deaths due to the virus. In Ireland, up to early September, 831 people have had laboratory confirmed pandemic flu, 86 were hospitalised, seven have been admitted to intensive care and two people have died. However, as laboratory testing is now only carried out for those with more severe illness, this under-represents the true

numbers of cases to date in Ireland. Using the numbers presenting to general practice with influenza like illness, the estimated total number of cases so far in Ireland is between 5,000 and 10,000.

For most people pandemic flu has caused mild to moderate illness, from which they recover at home without any specific treatment. However, there are many vulnerable people who may suffer a more severe illness, such as younger children, pregnant women and those with underlying diseases. Additionally, the virus can cause severe and fatal illness in young and healthy people, although the number of such cases is small. Studies have shown that between 20 per cent and 50 per cent of cases who have died have had no reported underlying illnesses. In spite of advanced medical technology using ventilators and other intensive care supports, it has not been possible to save all. Many deaths are due to development of organ failure. The latest number of deaths worldwide is 3,281 (figure published on the European Centre for Disease Prevention and Control website) with deaths occurring in countries with advanced medical facilities such as the US (n=593), Australia (n=160), Canada (n=72), and UK (n=70). In the Northern hemisphere these number of deaths have occurred out of the usual flu season and larger waves of infection are expected in the winter season.

The Pandemic vaccine is the best tool we have to prevent this illness. In previous influenza pandemics, millions of people have died worldwide. We have the opportunity to prevent this happening, once a safe effective vaccine is available. Clinical trials of pandemic H1N1 vaccines commenced in at least five countries in July 2009 and early results should be available in September. This vaccine is expected to begin arriving in Ireland from September/October 2009. It will be delivered in stages, so we will offer vaccine to high risk people first, along with healthcare staff and other essential workers.

SAFETY FIRST

As with every vaccine, vaccine safety is a major priority. Influenza vaccines have been used for more than 60 years and have an established record of safety in all

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age groups. Before being used, vaccines must pass many safety tests. These safety tests are conducted at each step in the vaccine development and to very high safety standards. The European Medicines Agency states that "decades of experience with seasonal influenza vaccines indicate that insertion of a new strain in a vaccine, should not substantially affect the safety or level of protection offered". People in Ireland will only be vaccinated after the vaccine has been licensed by the European Medicines Evaluation Agency (EMA).

Well-known side effects of influenza vaccines (as with other vaccines) are some redness or swelling around the vaccination site for a day or two. Some vaccinated individuals will experience fever, malaise, headache and aching muscles or joints. If these problems occur, they may last as long as 1-2 days. Serious adverse reactions, such as allergic reactions, are rare and it is important to remember that influenza vaccines cannot give someone influenza.

One potential side effect that some people worry about is Guillain-Barré Syndrome (GBS), because GBS was seen in some people who received the swine flu vaccine in 1976. GBS is an autoimmune disease, often preceded by a respiratory or gastrointestinal infection. It causes progressive muscle weakness and short-term paralysis. Most of the people who get GBS recover and are able to return to their normal lives and activities and in about 40 per cent of cases, no cause is found. Approximately 55-85 cases occur in Ireland each year, a rate of 1.5-2 cases per 100,000 population. Some studies have suggested that seasonal influenza vaccine



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could be associated with an increased risk of GBS with one case occurring for every one million persons vaccinated. During the 1976 influenza campaign in the US about 10 cases developed GBS for every million persons who were vaccinated. A recent UK study has shown that getting influenza illness is in fact a greater risk factor for GBS, with a 16 times increased risk of getting GBS in the 30 days after a influenza like illness. In this study, seasonal flu vaccine protected against GBS. As people who have previously had GBS are more likely to get it again, anyone who developed GBS within six weeks of a previous influenza vaccine or has developed GBS within the past year should discuss the risks and benefits of vaccination with their doctor. For people who have never had GBS, the benefits of influenza vaccination greatly outweigh any risk of vaccine-associated GBS.

USE OF THIMERSAL

Another concern that has been raised in media reports lately is the use of thiomersal as a preservative in one of the vaccines procured by the HSE. Thiomersal is a mercury-containing compound that has been used since the 1930s to prevent contamination in some multi-dose vials of vaccines. Thiomersal is not the same as methyl mercury, which can accumulate in the body and become toxic. Thiomersal contains a different form of mercury (ethyl mercury) which does not accumulate and is metabolised and removed from the body

much faster than is methyl mercury. A European review of the available evidence concluded that there is no evidence of harm from thiomersal in vaccines other than hypersensitivity (allergic) reactions (EMA Public Statement on Thiomersal and Safety of Thiomersal-Containing Vaccines dated 24 March 2004). In addition, the World Health Organisation has concluded that there is no evidence of mercury toxicity in infants, children, or adults exposed to thiomersal in vaccines. CDC have recently released a statement to say that pregnant women can receive influenza vaccine with or without thiomersal. Because pregnant women are at increased risk of complications from this influenza strain, and because a substantial safety margin has been incorporated into the health guidance values for organic mercury exposure, the benefits of influenza vaccine with reduced or standard thiomersal content greatly outweigh the theoretical risk, if any, of thiomersal.

Anyone who has had a severe (life threatening) allergy to eggs or to any other substance in the vaccine should inform their immunisation providers and discuss which vaccine is appropriate.

It has been shown that up to 25 per cent of healthcare workers can contract influenza in any one season. Infected health care workers, even if asymptomatic, can be a source of infection for their patients and families. A safe effective pandemic vaccine can save many lives, both from influenza and from the indirect effects of an overrun health service. In order to protect ourselves, our families, patients, co-workers and communities, it is very important that we get vaccinated as soon as the pandemic (H1N1) 2009 vaccination programme starts. In fact, it is our moral and ethical responsibility. Get vaccinated and stay healthy this winter.

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Additional material from Dr S Cotter, Dr D Igoe, Dr I Kelly and Dr E O’Connell.

KEY POINTS

- People in Ireland will only be vaccinated after the vaccine has been licensed by the European Medicines Evaluation Agency (EMA).
- For people who have never had GBS, the benefits of influenza vaccination greatly outweigh any risk of vaccine-associated GBS.
- The Pandemic vaccine is the best tool we have to prevent this illness.