

Facts and Figures (Continued)

- As of the end of October 2009, it was estimated that over 100,000 people in Ireland had contracted swine flu.
- The UK Government estimates that 12% of the population will have fallen ill with swine flu by the end of the winter flu season in April 2010.
- WHO estimate that the H1N1 pandemic flu virus could eventually affect up to 2 billion people globally.

Medical Costs

The H1N1 (swine) flu vaccine will cost countries between \$2.50 and \$20 per dose, based on their ability to pay, according to WHO. Ireland will pay €5 million for the 7.7 million doses they have ordered, while the UK are expected to pay £155 million for 130 million doses over the next four years.

Vaccine success stories

WHO, the CDC and the UN Foundation and UNICEF collaborate to improve vaccination coverage worldwide with positive results. Examples are:

- the reduction in estimated cases of Polio from 350,000 to 3500 worldwide between 1998 and 2000, and
- the 68% reduction in deaths from measles worldwide between 2000 and 2006.

Failure to vaccinate is believed to have severe consequences:

- WHO estimates that in 2002, 1.4 million deaths worldwide among children under 5 were due to vaccine-preventable diseases.
- without measles vaccinations, 2.7 million people would die.

Ireland and the UK have very high vaccination coverage rates (in the 80-90%) for vaccine-preventable diseases such as measles. However, from late 1999 until the summer of 2000, there was a measles outbreak in North Dublin. At the time, the national immunization level had fallen below 80%, and in part of North Dublin the level was around 60%. There were more than 100 hospital admissions from over 300 cases, and three children died. If enough people in a community are immunised against certain diseases, then it is more difficult for that disease to get passed between those who aren't immunised. This is known as herd immunity and only applies to diseases that are transmitted from person to person.

Legislation and Regulatory Authorities

The European Medicines Agency (EMA) is responsible for the scientific evaluation of applications for European marketing authorisation for medicinal products.

In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) is a government body responsible for regulating vaccines according to the Medicines Act of 1968. This Act requires medicines to be licensed before being allowed on the UK market. Some provisions of the Act have been superseded by the European legislation.

To satisfy the regulations, the MHRA considers:

- Do the advantages outweigh the disadvantages of taking the medicine?
- Does the medicine do the most good for the least harm for the most people who will be taking it?
- Are the side effects acceptable?

In Ireland, human medicines require marketing authorisation from the Irish Medicines Board.

Religious influences

Some people refuse vaccinations based on their religious beliefs, either because they don't accept health care intervention in general, or because there are components in vaccines which are from animal sources.

Sources and Further Reading

For a collection of relevant news stories and references, visit the website of one of the DSI co-ordinating centres:

www.remedi.ie <http://apc.ucc.ie> www.bdi.ie www.rcsi.ie www.cit.ie
www.w5online.co.uk www.crossborder.ie www.crann.tcd.ie www.clarity-centre.org

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Vaccination Against Seasonal and Pandemic Flu

Debate Motion

This house proposes that the entire population should be immunised against seasonal flu and potentially pandemic animal influenzas such as swine flu.

Vaccines

A vaccine is a liquid that contains a weak version of a disease-causing bacterium or virus. This version of the disease is not contagious. Once you have caught a disease, you develop immunity to it. Vaccines work on this principle and mimic the disease. Some vaccines are injected into the body and some swallowed as a liquid. The bacteria or viruses (called antigens) trigger the body's immune system to create antibodies. Vaccines only provide enough antigens to trigger the immune system, which leads to protection against the disease in the future. If you later acquire a higher dose of the bacterium or virus, your antibodies recognize and destroy them immediately, preventing you from becoming ill. Antibodies are disease-specific, so the vaccine for one disease will not protect you from another disease.

Vaccination is well established as the most effective means of preventing flu. However, developing a vaccine for a particular flu virus is only possible once the virus is identified and samples have been obtained. Vaccine development is costly and may take up to six months to produce enough to treat many people.

There are several ethical concerns related to vaccination and swine flu, which we discuss below. First we explain seasonal influenza and other animal influenzas and also the stakeholders with different interests in flu vaccination.

What is Seasonal Flu?

Influenza is a highly infectious acute respiratory illness caused by the influenza virus. Influenza affects people of all ages, outbreaks of influenza occur almost every year, usually in winter and hence it is also known as seasonal flu. While most people recover within a week flu can cause serious illness and death, especially in the very young and in the elderly. A flu vaccine is produced every year to protect against flu.

Flu is often self limiting with most people recovering in 2-7 days. Serious respiratory complications can develop, including pneumonia and bronchitis, to which older people and those with certain chronic medical conditions are particularly susceptible. These illnesses may need hospital treatment. The World Health Organisation monitors the strains of influenza circulating every year, recommending which strains to put in each season's vaccine batch.

What are potentially pandemic animal flus?

- **Bird flu** (avian influenza) is an infectious disease of birds caused by a certain type of flu virus. Poultry (chickens and turkeys etc.) are particularly susceptible, however. There are many different types or 'strains' of bird flu. Of all the flu viruses that circulate in birds, the H5N1 strain is the most worrying, because it has 'crossed the species barrier' to infect humans.

As of September 2009, there had been 442 cases and 262 deaths from avian influenza since the outbreak in 2003, with the infection rate having slowed dramatically (WHO 2009)

- Swine flu or H1N1 flu virus is a type of influenza that usually affects pigs. It can also be transmitted to humans, and from human-to-human. It was officially declared as a pandemic on June 11 2009 (WHO).

Pandemic (H1N1) 2009 is a new virus that has not circulated among humans before. This virus is different from previous or current human seasonal influenza viruses. It is transmitted by inhaling infected droplets expelled by coughing or sneezing or by touching contaminated hands or surfaces, the same as the normal seasonal flu.

The symptoms are similar to the symptoms of 'ordinary' flu. Typically, people with swine flu have a high temperature (38°C or greater). They also have at least two of the following symptoms: cough, sore throat, headache, runny nose, general aches and pains, vomiting or diarrhoea.

What are potentially pandemic animal flus? (Continued)

So far, experience with this virus suggests that most people fully recover. However, complications occur in some people and they can be serious and life-threatening. The most serious complication is pneumonia (lung infection) which may develop and may be fatal. People who require intensive care usually do so as a result of developing pneumonia about three to five days after first experiencing swine flu symptoms. In some cases this progresses to a condition called adult respiratory distress syndrome; the seriously ill patient requires mechanical ventilation and other specialist procedures at this point. The flu virus can also trigger serious complications such as kidney failure and inflammation of the brain in a small minority of people.

Apart from vulnerable populations, severe cases and deaths have occurred in young and previously healthy adults, and less often children.

According to the WHO pandemic alert, the world is presently in phase 6 in a table of 6 phases of increasing severity. Phase 5 is a strong signal that a pandemic is imminent and that the time to finalize the organization, communication, and implementation of the planned mitigation measures is short. Phase 6, the pandemic phase, is characterized by community level outbreaks in at least one other country in a different WHO region in addition to the criteria defined in Phase 5. Designation of this phase indicates that a global pandemic is under way.

Stakeholders

Vaccination against flu and potentially pandemic animal flus involve many parties:

- Health care providers, who will be exposed to infected people.
- Vulnerable health groups, e.g. people with asthma, or people more likely to catch flu than others.
- Developing countries, where deficits in health care may increase spread of the illness.
- Global and national governing bodies, preparing for a pandemic.
- Pharmaceutical companies, who will gain financially from developing and marketing vaccines.
- The general public, who will be affected if there is a pandemic.

Key Terms

Antivirals: Antivirals are medicines that are effective against viruses such as flu. Antibiotics have no effect against illnesses caused by viruses. Antivirals are not vaccinations; they only treat and do not prevent disease. Swine flu has been reported to be resistant to some antivirals (Reuters 2009).

H5N1 vaccine: Two H1N1 vaccines have been developed and approved so far: Pandemrix and Celvapan.

Pandemic: The word 'pandemic' describes an epidemic that affects the whole human population. Previous pandemics include the Black Death in the 1300s, the Spanish flu 1918-19, Asian flu in 1957, Hong Kong flu 1968-72, and SARS in 2003.

Ethical Questions

Is it necessary to vaccinate the whole population from seasonal flu?

Currently, the HSE recommends that the following people should be vaccinated each year;

- Persons aged 65 years or older
- Younger people with certain illnesses including chronic lung, heart or kidney disease, diabetes or those with a suppressed immune system.
- Residents of nursing homes, old peoples' homes, and other long stay facilities
- Home Carers of older people and younger people with above illnesses
- Health Care Workers

The vaccine offers up to 70 - 90% protection from the flu virus and lasts about one year. Annual vaccination with the most recent strains is recommended. It is not currently recommended to vaccinate the entire population against seasonal flu.

Current situation with swine flu vaccine

Two vaccines have been purchased by the HSE for the Irish population (HSE purchased)

- Pandemrix (GSK)
- Celvapan (Baxter)

Both have been recommended for authorisation by European Medicines Agency (EMA).

A national swine flu pandemic vaccine campaign organised by the Health Service Executive (HSE) commenced in November 2009. Pregnant women and people with chronic underlying disease, aged between six months and 65 years were vaccinated first, due to data showing that about 50 per cent of those who have required hospital

Ethical Questions (Continued)

admission in Ireland to date have been in "at-risk" categories. In the case of pregnant women infected with the pandemic (H1N1) 2009 bug, it is estimated they are four times more likely to require hospital admission than the general population. People who require intensive care usually do so as a result of developing pneumonia about three to five days after first experiencing swine flu symptoms.

It has been shown that 20-30% of deaths occur in individuals with no obvious risk factor identified (Health Protection Surveillance Centre 2009).

Will the swine flu vaccine be safe?

According to WHO, vaccines have to be available quickly and in large quantities to have the greatest impact. They added that fast-track approval will not jeopardise safety.

Some concerns have been raised because of serious side effects and 30 deaths seen during a U.S. swine flu vaccination in 1976. Experts say vaccine production and purity levels had improved significantly since but safety issues could arise during a pandemic when a vaccine is administered on a mass scale, even if they did not show up in safety trials. As a result, countries are being advised to conduct intensive monitoring as the vaccination campaign goes on.

Because the pandemic virus is new, both non-clinical and clinical testing is being done to gain essential information on immune response and safety. The results of studies reported to date suggest the vaccines are as safe as seasonal influenza vaccines (WHO 2009).

Vaccinate selectively?

The vaccination process in Ireland will be done in three phases:

Phase One: Vaccinating healthcare workers

Phase Two: Vaccinating at risk groups and also emergency services personnel

Phase Three: Mass vaccination programme, vaccinating the general population.

Everyone will need two separate doses of the vaccine. Ireland expect to take delivery of 7.7 million doses of the vaccine in total (DoHC 2009).

Prioritising vaccination for specific groups in this way allows those who most need the vaccine to receive as stocks continue to arrive. However, some groups who are lower in the priority list may feel that this type of selective vaccination is unfair. The fact that many otherwise healthy people have become seriously ill as a result of swine flu could mean that perhaps it is equally dangerous in the entire population.

Financial risk?

Vaccines are disease specific. This means that once the virus has changed slightly, for example into a version which can be transmitted between humans, the vaccine manufactured from the previous virus type will be ineffective. There are suggestions that investment in developing more antivirals would be more useful.

A possible solution to raise funds for vaccine development is to charge for vaccines. However, you may feel that this is unfair because it discriminates against people who can't afford additional health costs. Once again, a selective system for payment could be imposed, for example with free vaccines for essential services, high medical risk and low income groups, and a small payment by everyone else.

- During the 'Spanish flu' epidemic, which first hit Britain in May 1918, 228,000 people died in Britain. By the end of 1919, 50 million people had died worldwide (www.eastlondonhistory.com).
- A 2003 US study estimated that annual influenza epidemics resulted in an average of 610,660 life-years lost, 3.1 million hospitalized days, and 31.4 million outpatient visits, at a cost of \$87.1 billion (Molinari et al, 2007).
- Approximately 6% of confirmed H1N1 2009 influenza deaths in the US have been in pregnant women, although approximately 1% of general population is pregnant at any given time). (Source CDC 6/10/2009)
- In Ireland, it is estimated that up to 25% of the Irish population could contract the flu in a 'worst case scenario' (Dept. Health and Children & Health Service Executive).