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EDITORIAL

Influenza A (H1N1) 2009
To vaccinate or not to vaccinate?

*Ali A Al-Jabri and Sidgi S Hasson

انفلونزا A (H1N1) 2009
أخذ اللقاح من عدمه

علي بن عبدالله الجابري، صدقي حسن

Beginning in March 2009, an outbreak of influenza in North America was found to be caused by a new strain of influenza virus, designated Influenza A (H1N1) 2009, which is a reassortant of swine, avian and human influenza viruses.[1] The World Health Organization (WHO) declared Influenza A (H1N1) 2009 to be a pandemic predicting that a third of the world's population would eventually be infected.[2] In order to come to grips with such a dire situation, vaccines are being tried in various parts of the world. This article highlights the pros and cons of using vaccine for a disease that is akin to seasonal influenza.

Influenza virus is an enveloped virus, of the *Orthomyxoviridae* family, which has a unique capacity for changing its genetic material continuously, based on genetic variation and molecular features that are inherited from the virus family.[1] The surface proteins of the virus are highly variable due to genetic mutations which lead to changes in up to 50% of the amino acid with the continuous ability to cause infection. The viral genome is segmented, with eight segments of its RNA molecules. When infection is caused by several different influenza genotypes, such segments can be randomly re-assorted resulting in hybrid genotypes with some segments derived from one virus strain, whereas, the others are derived from a second strain.[3]

Over a thousand cases of Influenza A (H1N1) were identified in the first month, mainly in the United States of America (USA) and Mexico; thereafter thousands of cases were identified and reported all over the world. Appropriate actions concerning Influenza A (H1N1) 2009 need to be made based on facts discovered by scientists; however, these actions should not to be affected by political, legal, financial or any other interests.[4] Every influenza outbreak, or pandemic, is unique and therefore its features have to be carefully studied and evaluated before making any actions and/or recommendations. However, pandemic preparedness for some microorganisms may have to anticipate potential pandemic characteristics even before they develop in order to take pro-active actions and make pro-active recommendations.

Generally speaking, to protect individuals from a particular disease immunisation is essential. Immunisation can be active (vaccination) or passive, natural or artificial. An unintentional (i.e. natural) immunisation can also happen when an individual is inadvertently exposed to an infectious agent. Through vaccination, individuals receive a modified antigen that may consist of attenuated or killed organisms, subcellular components or detoxified toxins that trigger an immune response. The outcome of vaccination is that a subsequent exposure to the unmodified antigen will lead to rapid activation of the immune system to eliminate that pathogen before it can cause disease. Unfortunately, no vaccination is without risk. This was certainly evident with the swine influenza epidemic which occurred in 1976, when there was a rush to protect

Division of Immunology, Department of Microbiology and Immunology, College of Medicine and Health Sciences, Sultan Qaboos University, Muscat, Oman

** To whom correspondence should be addressed. Email aaljabri@squ.edu.om*

individuals who were at risk (especially infants and the elderly). Neurological complications such as Guillain-Barré syndrome and others were observed to arise from the vaccine.[5] This has therefore caused an alert and raised a serious concerns about the safety and efficacy of receiving the H1N1 vaccine against the current Influenza A (H1N1) 2009 virus.

Current issues and concerns of the Influenza A (H1N1) 2009 vaccine

Media and broadcasts confirmed that many people worldwide expressed their concern about the safety and efficacy of the newly developed H1N1 vaccine. Many questions were raised such as: 1) Do we have enough knowledge about the side-effects of the newly developed vaccine, such as Guillain-Barré Syndrome, which can lead to paralysis and even death? 2) Are there any other side effects that we don't yet know about? and 3) Is it worth the risk to be vaccinated when the vaccine does becomes available?

The influenza virus is known to be one of the most complex and confusing of all viruses due to its continuous genetic mutations. Unlike other viruses such as measles, which stay the same year after year, every one to three years, influenza viruses mutate and therefore, people at risk have to get vaccinated yearly. Early each year, health organisations worldwide routinely decide which influenza strains will be included in the subsequent seasonal influenza vaccine. However, one of the current dilemmas is the possibility that by the time the vaccine becomes available later on in the year, usually in September or October, the viruses may have undergone genetic mutation. Therefore, the question then will be raised whether it is of practical use to expose human beings to the vaccine and its possible side effects.

The concerns about the new vaccine are mainly due to what happened at Fort Dix in 1976, and was linked to a swine flu-like outbreak. In 1976, over 40 million people received the H1N1 vaccination over a period of a few months.[5] The incidence of Guillain-Barré syndrome at that time was about one in 50,000. Guillain-Barré syndrome is a rare clinical disorder where the body's immune system attacks the nerves, causing weakness and numbness to the arms and legs and sometimes even paralysis. The above figure compares to about one in a million people who normally develop the syndrome from a seasonal influenza vaccine. Moreover, Guillain-Barré syndrome occurs naturally following upper respiratory illnesses, digestive illnesses and is also rarely associated with some drugs and vaccines. The new H1N1 vaccine is expected to be vigorously tested before it can be available to the public. In fact scientists cannot be sure that no incidence of Guillain-Barré syndrome will occur this time, but based upon the differences in the vaccine production in 1967 versus 2009 a similar incidence of vaccine related Guillain-Barré syndrome is not anticipated. However, if such rare side effects should occur, this would not be known until hundreds of thousands or even millions people had received the new vaccine.

In addition to the above, it is important to know the contents of the newly developed vaccine, and what a regular influenza vaccine normally contains.[6] There is also another concern as to whether the newly developed vaccine will be effective at all.

It may be understandable that individuals who are in good health, and have no other risk factors, express reservations about receiving the vaccine because if they become infected with H1N1 they may develop natural immunity against the virus and in the worst scenario if they do develop any clinical complications they will still have access to the antiviral treatment that is currently available. However, it would be risky for individuals who have other health problems and for children not to receive the vaccine when it becomes available. The risk groups have already been identified by the WHO and included in the Centre for Disease Control (CDC) recommendations (see below).

Advantages of the Influenza A (H1N1) 2009 vaccine

Vaccines are the most powerful public health tool for the control of influenza infection. In the past 30 years, many hundreds of millions of doses of trivalent H1, H3 and B influenza vaccines have been administered without significant clinical complications, while saving countless lives. Currently, the CDC in the USA has already isolated the new Influenza A (H1N1) virus and modified the virus so that it can be used to make hundreds of millions of doses of the vaccine.[7,8]

Vaccine manufacturers have used the modified virus materials to produce vaccines.[9,10,11] Making a vaccine is a multi-step process which can take several months to complete. Candidate vaccines must be tested through clinical trials over the few months following production.

Despite all the concerns stated earlier, many people who were around during the swine influenza outbreak in 1976 have been found to have some immunity to H1N1.[11,12,13,14,15] Also, people over the age of 50 who have received annual influenza vaccines for most of their adult lives (all influenza vaccines contain some form of the H1N1 virus) also appear to have partial immunity.[11,13] People are strongly advised to receive the seasonal influenza vaccine because, during the H1N1 influenza virus pandemic, there may be other strains of influenza making their rounds, and people should not leave themselves susceptible to them.[11,13] The 1976 swine influenza virus and the Influenza A (H1N1) 2009 virus are different enough so that its unlikely that a person vaccinated in 1976 will have full protection from the 2009 H1N1. People vaccinated in 1976 should still be given the H1N1 2009 vaccine.[7]

It is anticipated that both seasonal influenza and Influenza A (H1N1) 2009 vaccines may be administered at the same time, despite the fact that seasonal vaccines are already available. The usual seasonal influenza viruses are still expected to cause illness this autumn and winter. So, at risk individuals are encouraged to get their seasonal influenza vaccine as soon as it is available.[7]

The CDC's Advisory Committee on Immunization Practices (ACIP) has recommended that only certain at risk groups among the whole population are highly encouraged to receive the A (H1N1) 2009 vaccine immediately it becomes available. These target groups include pregnant women, people who live with or taking care for children younger than 6 months of age, health care and emergency medical services personnel, persons between the ages of 6 months and 24 years old, and people of 25 through 64 years of age who are at higher risk of A (H1N1) 2009 because of chronic health disorders or compromised immune systems.[7,8]

It is expected that the Influenza A (H1N1) 2009 vaccine will have a similar safety profile to that of seasonal influenza vaccines, which have a very good safety track record. Over the years, hundreds of millions of people have received seasonal influenza vaccines. The most common side effects following influenza vaccinations are mild, such as soreness, redness, tenderness or swelling where the shot was given. The CDC expects that any side effects following vaccination with the Influenza A (H1N1) 2009 vaccine would be rare.[7] However, if side effects occur, they will likely be similar to those experienced following seasonal influenza vaccines.[7] If these problems occur, they usually begin soon after the vaccination is given and last 1 to 2 days. Life-threatening allergic reactions to vaccines are very rare.[7,8] If they do occur, it is usually within a few minutes to a few hours after the vaccination is given. Additionally, the CDC is planning to work with numerous partners, including other federal agencies, state and local health departments, professional organisations, and academic institutions to follow individuals actively after vaccination and to monitor for any potential adverse events.[7,8] Seasonal influenza vaccines are known to be highly effective in preventing the disease. The expectation is that a vaccine against Influenza A (H1N1) 2009 would probably work in a similar fashion to the seasonal influenza vaccines. The CDC believes that the benefits to be gained from vaccination with the Influenza A (H1N1) 2009 vaccine will far outweigh the risks.[7,8]

Pregnant women, children and teens are the high risk groups who are susceptible to the clinical complications due to infection with H1N1. Such complications include death so these groups should be vaccinated no matter what.[7] Other groups, however, may have some leeway to decide on vaccination or refuse it. Individuals who had a documented case of H1N1 during the 2008-2009 influenza season have probably acquired partial immunity. But if the current strain changes between now and December, people could be highly susceptible to contracting the new virus without any immunity. Despite the decline in the pandemic, those at risk should be vaccinated in case there is a second wave of infection. Overall, development of antiviral vaccination has long been recognised as the most cost efficient use of public money in the entire health field, both in saving lives and for economic impact.

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