Brochure Outline – Influenza A Vaccines

Title: Getting The Word Out About Flu Vaccination

Group 3 BIOL 302 Bacteria, Viruses, and Health

**\*PLEASE FEEL FREE TO ADD, TAKE OUT, SUGGEST, ALTER**

**Introduction**

The purpose of the Group 3 project 2 assignment will be to create an informational pamphlet to communicate a message of the importance of influenza vaccination. The informational pamphlet will focus on the importance of the planning of influenza vaccine production and distribution to prevent the shortages of vaccine that occurred during the 2009 H1N1 flu season in which many people were unable to receive flu vaccinations. Also the pamphlet will summarize the importance of researching and developing new influenza vaccine research and production in order for governmental and medical representatives to be well prepared for potential forthcoming influenza epidemics or pandemics (Schwartz, 2015).

**Background**

During the flu pandemic of 2009-2010, the nation’s health care system was caught off guard and the USA experienced a major shortage of the 2009-H1N1 influenza vaccine. Many individuals were not able to receive the vaccination simply because there was not enough to go around. The US health care system, including the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) should not wait for another pandemic situation to occur like the 2009-H1N1 influenza to prepare for the future.

New technologies and techniques should be utilized that have already been approved by the FDA available for influenza vaccines that could increase the supply available in case of a major flu outbreak. A campaign to get the word out to the general health care community including drug development companies and Federal, State and local officials should be started to bring attention to this serious matter. Our team is developing a strategy to spread the word of the sense of urgency to pursue alternate influenza vaccine production to increase the nation’s supply of flu vaccine to be prepared for the next flu outbreak (FDA, 2013).

**About Influenza A and Vaccines**

A. The genus, *Influenzavirus* *A,* is an acute contagious virus from the viral family Orthomyxoviridae that infects epithelial cells of the respiratory system. This virus causes seasonal diseases every year in the United States. Influenza A is easily transmitted by inhaled viral particles via droplets or aerosol. (Schwartz, 2015)

B. Symptoms of Influenza A are: fever/chills, cough, sore throat, runny or stuffy nose, body aches, lethargy, vomiting, and diarrhea. (CDC, 2014)

C. Strains of Influenza A and subtypes: categorized by surface proteins hemagglutinin (H) and neuraminidase (N). 18 different (H) subtypes and 11 different (N) subtypes. (H1 – H18 and N1 – N11) Known strains found in humans are influenza A (H1N1) and (H3N2). (CDC, 2014) In 2009, a newly mutated H1N1 “Swine Flu” virus was the first influenza pandemic in over 40 years; people had little to no immunity against the virus, health care systems were overwhelmed, and vaccine manufacturing was moderate. (Flu.Gov, 2015)

D. **Viruses selected for development**

1. Strains for Influenza A Vaccine:production and viral strains used in influenza vaccines contain one or more influenza A viruses, H1N1 and H3N2.  Influenza A viruses frequently progress inantigenic drifts in their H and N antigen(s), former vaccines are ineffective against newly formed influenza A viruses. Viruses must identify with past historic records with origin of strain and its new mutation. These strains are isolated from mammalian and egg cells. (WHO, 2005, Annex 3) The World Health Organization and CDC take type A-like viruses from different geographical regions, an isolate number of the new mutation strain from the parent strain (H1N1 or H3N2) and year produced. The example for selection would read: Type A/California/7/2004 (H3N2) – like virus. These viruses are then developed into inactivated and live attenuated vaccines. (Kamps, B. et al, 2009)

**E. Limitations of egg-based vaccine manufacturing**

Egg based flu vaccine has been the customary method of production for 60 years. The advantage of this method is that it is safe and well proven. The main disadvantage of egg-based flu vaccines is that the manufacture process can take approximately four months from time of influenza strain selection for the vaccine. Considering all other factors that go into the manufacturing and distribution of the vaccine, the possibility of shortages is high if there is an epidemic outbreak of the flu (HSA, 2014).

**F. FDA Influenza A approved vaccines:**

1. Inactive Injectable

Currently, the FDA has four approved brands injectable Influenza A (H1N1) 2009 monovalent vaccines in place. The current brands have a well proven track record of safety and effectiveness. The vaccines are approved for individuals from the age of 6 months and older and come in single –dose, pre-filled syringes or multi-dose vials and the vaccine is administered through an intra-muscular injection (FDA, 2013).

1(g) FDA approved brands: Influenza A (H1N1) Monovalent Vaccine Manufactures: CSL Limited; ID Biomedical Corporation of Quebec; Novartis Vaccines and Diagnostics Limited; Sanofi Pasteur, Inc.

2. Attenuated Nasal

Currently the FDA has approved the use of an intranasal influenza vaccine for types A and B of the virus. The vaccine is only approved for individuals between the ages of 2-49. A single dose contains (0 .2ml) and is administered with a sprayer spitting the dosage between both nostrils (FDA, 2013).

2(g) FDA approved brand: FluMist, Manufacturer: Medimmune, LLC

G1. **Risk of Vaccines:**

* Foetal abnormalities which ones are associated with the influenza vaccines.
* Guillain -Barre Syndrome (GBS)
* Reports of death exist (Read Healthimpactnews.com 2014 and find out what these conditions mean), Chronic inflammatory demyelinating polyneuropathy, Rheumatoid arthritis, Shingles, Bell’s palsy.

G2. **Disadvantage of Influenza vaccines**

* Side effects-which are similar to flu symptoms themselves although mild
* Flu shot may cause mild soreness, fever, aches and in rare cases it can cause severe allergic reactions which are serious.
* Nasal spray may cause running nose, wheezing, headache, vomiting, muscle aches, fever
* There are reports of ineffectiveness in elderly people who are unfortunately most at risk of influenza.
* Effectiveness of influenza vaccines is reported to vary from 70-90%
* The vaccine does not give lifelong immunity,
* Nasal spray is less effective in people who have already been exposed to the influenza virus
* Contraindications have been reported.

H. **Other FDA approved influenza vaccines advantages and limitations:**

The manufacture and distribution of influenza vaccines in the USA is monitored and regulated by the Food and Drug Administration (FDA). Conventionally, the flu vaccine production process has involved poultry egg-based process that is dependent on the supply of qualified eggs and time of up to four months for manufacturing. Recently the FDA has been involved in the development of non-egg based vaccines.

A new FDA approved flu vaccine called Flucelvax in which the vaccine is grown in cells of mammals instead of eggs. Advantages of cell based flu vaccine are that the cells can be frozen for later use and the supply of eggs is not a factor. Also some vaccines to not grow well using egg technology. Some limitations are that cell based vaccines are relatively new and the safety and reliability are not time proven.

Another new FDA approved vaccine for influenza does not use actual influenza viruses or eggs in the manufacturing process. Instead flu virus proteins are genetically modified using insect cells that would trigger an individual’s immune system to fight the flu. Advantages of this process is that neither flu viruses nor eggs are required enabling the possibility of mass production to deal with flu pandemics and epidemic more effectively (FDA, 2013).

I. **Conclusion:**

For the 2015-2016 US influenza season, the FDA has a committee that met on March 4, 2015 to choose the influenza virus strains for production of the trivalent formulation influenza vaccine for the upcoming flu season. The FDA then releases the information to the vaccine manufactures for production and distribution of the vaccine products. Interestingly the committee examines and evaluates characteristics of recent influenza strains from around the world and also serological responses to the previous season’s vaccines to determine the new vaccine formulations. For the 2015-2016 influenza season the trivalent flu vaccine formulation will consist of the following strains (FDA, 2015.

A/California/7/2009 (H1N1)-like virus

A/Switzerland/971593/971593 (H3N2) –like virus

B/Phuket/2013-like virus

The committee also suggested a quadrivalent flu vaccine that would add to the above strains the following strain (FDA 2015).

B/Brisbane/60/2008-like virus

With the upcoming influenza season approaching it is vitally important that global, federal, state and local health organizations work together with influenza vaccine manufacturers to ensure that there is enough vaccine available to the public. It is also important that the public understands the importance that all individuals getting vaccinated to prevent the possibility of a wide spread flu pandemic and unnecessary illnesses and deaths.

References:

CDC. (13 August, 2014) “Flu Symptoms & Severity”. *Centers for Disease Control and Prevention*. Retrieved July 14, 2015 from <http://www.cdc.gov/flu/about/disease/symptoms.htm>

CDC. (19 August, 2014) “Types of Influenza Viruses”. *Centers for Disease Control and Prevention*. Retrieved July 14, 2015 from <http://www.cdc.gov/flu/about/viruses/types.htm>

FDA. (19 Feb, 2013) “Influenza Virus Vaccine, Trivalent, Types A and B”. *U.S. Food and Drug Administration*. Retrieved July 14, 2015 from <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094045.htm>

FDA. (15 July, 2015) “Influenza Virus Vaccine for the 2015-2016 Season”. *U.S. Food and Drug Administration*. Retrieved July 17, 2015 from <http://www.fda.gov/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/post-marketactivities/lotreleases/ucm454877.htm>

HSA. (23 Sep, 2014) Retrieved July 14, 2015 from <http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Consumer_Information/Public_Advisories/Influenza_A_H1N1_information/H1N1_Vaccines/understanding-vaccines--vaccine-development-and-production.html>

Kamps, B., Hoffmann, C., Preiser, W. (2006 – 2009) Vaccines. *Influenza Report – Flying Publisher.* Retrieved July 15, 2015 from <http://www.influenzareport.com/ir/vaccines.htm>

Schwartz, G.N. (12 July 2015) “About Influenza Viruses”. *UMUC BIOL 302 Course Content Project 2.* Retrieved July 14, 2015 from  <https://learn.umuc.edu/d2l/le/content/69220/viewContent/4096548/View>

USDHHS, (n.d.) “H1N1 (originally referred to as Swine Flu)”. *FLU.GOV, U.S. Department of Health & Human Services*. Retrieved July 14, 2015 from <http://www.flu.gov/about_the_flu/h1n1/index.html>

USDHHS (16 April, 2015) “Vaccination & Vaccine Safety”. *Vaccines.gov: U.S. Department of Health & Human Services*. Retrieved July 14, 2015 from <http://www.vaccines.gov/diseases/flu/>

WHO. (2005) “Annex 3” - Recommendations for the production and control of influenza vaccine (inactivated). *World Health Organization,* WHO Technical Report Series, No. 927.  Retrieved July 14, 2015 from <http://www.who.int/biologicals/publications/trs/areas/vaccines/influenza/ANNEX%203%20InfluenzaP99-134.pdf?ua=1>

WHO. (2005) "Annex 4". Retrieved July 14, 2015 from <http://www.who.int/biologicals/areas/vaccines/influenza/TRS_977_Annex_4.pdf?ua=1>

NIAID (Jan, 2008) “Understanding Vaccines. What They Are How They Work”. *U.S. Department of Health and Human Services, National Institutes of Health*. Retrieved July 14, 2015 from <http://www.niaid.nih.gov/topics/vaccines/documents/undvacc.pdf>  (pg 36 – 37)

Grohskopf, Lisa, et.al. (2014-15). "Prevention and Control of seasonal influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices". United Sates, Influenza season.