

US Pandemic Planning Update VI – strong vaccine progress to date

LONDON, UK----12th January 2009----ExpertREACT. Recently the US Department of Health and Human Services (HHS) Secretary Levitt gave an update on the continued deployment of the \$7.1 billion US national pandemic plan mobilized by President Bush in 2005. Although some consider that attention to the pandemic threat and preparedness has diminished in the lay press, the recent HHS update suggests much progress has been made especially with regard to vaccines

Influenza pandemics, which are distinct from seasonal influenza, are a serious threat to global human health. In the 20th century there have been three significant influenza pandemics (1918 A/H1N1, 1957 A/H2N2 and 1968 A/H3N2). Each pandemic has been associated with high clinical attack rates (25-35%) and case fatality rates. In the 1918 pandemic known as “Spanish flu” fatality rates were 4-5 times (2-2.5%) compared with 1957 and 1968. Indeed, it is commonly cited that the 1918 pandemic or killed more young men than World War I itself with estimates of 50-100 million deaths. Bearing in mind the size of the global population today, even a “mild” influenza similar to that in 1957 and 1968 could kill millions of people.

Pandemics occur when a new subtype of influenza A emerges in humans which are capable of spreading efficiently. Because generally there is little or no pre-existing immunity, a pandemic influenza virus produces clinical illness normally associated with a virus-induced response of the victim’s immune system or “cytokine storm”. Deaths also occur due to secondary bacterial pneumonia’s that infect the lungs weakened by influenza. Influenza pandemics also cause significant economic and societal disruption. Although distinct from influenza, even SARS (a novel coronavirus) over a six-month period in 2003 caused \$40 billion economic losses in the Asia-Pacific region (1).

Experts commonly believe that the next influenza pandemic is imminent and are particularly concerned about the current influenza strain H5N1 which has spread rapidly in bird populations in SE Asia. H5N1 has caused high mortality and occasionally infecting humans with around 50% of cases being fatal. As of December 3rd 2008, 67 cumulative countries have experienced H5N1 avian influenza in animals which is an alarming increase on the 11 countries counted in 2004 (2). Over the same time period confirmed H5N1 Avian influenza deaths in humans have reached 245, again a significant increase upon 2004. H5N1 infections in humans potentially occur as a result of direct contact with infected birds; however, it is of concern that a simultaneous infection of human influenza and H5N1 could cause genetic reassortment forming a new virus that can be spread from human-to-human.

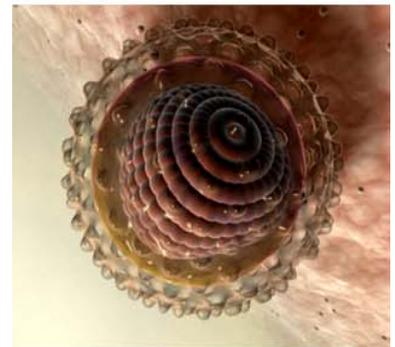
Many governments around the world have drawn up detailed plans specifying how they would deal with an influenza pandemic once its emergence was detected. Generally the objectives of a pandemic influenza preparedness program are to maintain national security, critical infrastructure and provide healthcare/community support to the general population. All these elements would be under severe strain should a pandemic arise. To exemplify the importance of pandemic preparedness planning, in the US the task has been given in addition to the US Department of Homeland Security which was initially formed after the September 11th terrorist attacks.

Pandemic preparedness plans are multifaceted in their countermeasure proposals to limit the impact of a pandemic. Along with an emphasis on individual’s “self care”, plans have detailed the stockpiling of antiviral drugs such as Tamiflu (oseltamavir) and Relenza (zanamavir) which can be used to treat individuals with acute pandemic illness and prevent virus spread. To date, collectively US states have purchased 22 million treatment courses of antivirals (2).

A large focus is also placed on ensuring mechanisms are in place to ensure the swift and efficient production of pandemic specific influenza vaccines using both egg-based and cell-based systems. Most governments have goals to provide pandemic specific vaccine to their total population but are cognizant that this would unavoidably take place over several months. In addition, a pandemic specific vaccine (likely 2 doses, 1 month apart) will probably more limit the second “wave” of the resultant pandemic rather than the first. Interestingly, in the latest US HHS update over \$1 billion in funding has been provided to six vaccine manufacturers to increase manufacturing capacity of cell-based systems to at least 240 million courses.

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It is widely believed that cell-based systems could produce the pandemic specific vaccine faster than traditional egg-based methods although currently the system is not yet US approved for seasonal flu. Vaccine companies such as Novartis Vaccines have a strong interest in cell-based influenza systems.

Other government measures have included the stockpiling of H5N1 pre-pandemic vaccines with the assumption that vaccine could provide cross-protective priming immunity to the eventual pandemic strain. Animal data also suggest that vaccination by human H5N1 vaccines produced by viruses of one clade may confer protection against challenge by H5N1 from other clades. Downsides are that H5N1 influenza vaccines generally elicit lower immune responses than seasonal influenza vaccines and less is known with regard to their safety and potential effectiveness in differing target populations.

The US government has procured 12.2 million treatment courses of H5N1 vaccine mainly allocated to support clinical trials and protect "front-line" healthcare workers, first responders and other critical tier 1 workers. The UK Department of Health (DoH) is taking a similar approach with H5N1 pre-pandemic vaccine reserved for National Healthcare Service workers (NHS) (3). Individual government measures are in addition to the World Health Organisation (WHO) stockpile initiative for pre-pandemic vaccines which could potentially contain 50-100 million doses (4).

Most major commercial manufacturers are keen to promote their H5N1 vaccine technology with GlaxoSmithKline, Novartis and Sanofi Pasteur having advanced or approved programs. For example, in May 2008, GSK announced that the EU commission granted marketing authorisation for Prepandrix™ the first licensed pre-pandemic vaccine in all 27 EU member states (5). At the time, GSK stated they had sold £146 million of bulk antigen in 2007. Rival Sanofi Pasteur received payment of \$197 million in the Q2 2008 as part of its multi-year contract with US HHS to supply H5N1 bulk antigen (6). The company had already received \$126.9 million in 2007. It appears pandemic flu vaccine preparedness is progressing well because of public/governmental fear but also because it is good business.

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