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How well is the industry prepared to fight H7N9 bird flu?

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During March 2013, the world woke up to yet another dreaded bird flu attack that infected humans through poultry. Two months have gone by and biopharma majors across the world have begun preparations to develop a vaccine for this new strain of virus, labeled H7N9, which has killed a quarter of the 129 people it infected.

Avian Influenza A or H7N9, which was detected in China during March this year, spread from Shanghai and affected five other Chinese cities by the end of April. According to the WHO, it has so far infected 129 people, killed 31 people and has managed to travel to Taiwan, which has also reported infection cases.

Many companies have tested the strains that has been made available by the Chinese health department through the World Health Organization (WHO). Although these firms claim that the vaccine is ready, issues such as mass production, swift availability in affected regions of the world and concerns related to intellectual rights over the development process are still acting as hurdles towards effective prevention of H7N9.

"The individuals involved in WHO's Global Influenza Surveillance and Response System (GISRS) network look at the viruses and then determine which is the most appropriate strain to use for development of potential vaccines. Once such candidate vaccine viruses are available, it will be announced by the WHO and be made accessible to all vaccine manufacturers worldwide. That is now happening for H7N9. The vaccine itself is made by the companies and is regulated by relevant national authorities and not by the WHO," a senior WHO official informed BioSpectrum.

Vaccine majors like Australia-based CSL, US-based Greffex, Chinese biopharmaceutical giant Sinovac Biotech and others such as Adimmune Corporation from Taiwan are trying to cut down the timeline required for vaccine manufacturing. Being the first company that bagged regulatory approval for swine flu vaccine in 2009, Sinovac Biotech from China is currently in the preparation stage. The company has an annual production capacity of about 30-to-40 million doses of flu vaccine and claims that it will be ready with its first batch of vaccines for commercial use by late July.

"Before the release of the right seed strain, we are doing all we can in the preparation stage, such as storing enough chicken-

embryos, preparing staff, and putting the right equipment in place," stated Zou Yong, director, H7N9 vaccine project, Sinovac Biotech, at a recent press briefing. The vaccine prepared will cost the Chinese government $3.23 (20 Yuan) a vial. The company is under an agreement with China's Food and Drug Administration (SFDA), according to which the vaccine prepared by Sinovac for pandemic flu doesn't need to undergo clinical trial as the production method is pre-tested and approved.

Speed meets flexibility

Vaccine major from the US, Greffex announced in May 2013 that they have prepared the first comprehensive vaccine for H7N9 Avian Influenza using their proprietary Grevax technology. Known as pioneer in short development periods for a vaccine, Greffex's vaccine platform can now take large payloads too.

"Our vaccine platform was built with support from the National Institutes of Health (NIH) and National Institute of Standard and Technology (NIST). The platform focuses on the potent immunogenicity of adenovirus-based engineered vaccines to vaccine antigens resulting in a 'plug-and-play' design of vaccines for emerging diseases. Speed as well as flexibility is needed for vaccine design in order to combat emerging infectious threats," explained Mr John R Price, president and CEO, Greffex, at a global press briefing held at their headquarters earlier in May.

With the virus spreading to Taiwan, companies there too have begun earnest preparations for developing a vaccine. Claiming to be the only human-vaccine manufacturer in Taiwan, Adimmune Corporation requested the US Centers for Disease Control and Prevention and the WHO for the H7N9 virus strands needed to prepare a vaccine. These groups have agreed to provide the same to the Taiwan National Health Research Institutes (NHRI) by the end of May. "We will need only six-to-eight week's time to prepare a vaccine. We're using the H1N1 vaccine for which we already have license to make a mockup vaccine, to get quick approval from the government," Adimmune vice president Mr Simon Kao stated in the company's official statement.

The company that had in 2009 produced and distributed over 7 million doses, now aims to produce between 5 million and 10 million doses. With an ability to produce two million doses of the vaccine, Taiwan's National Health Research Institute (NHRI) said that it is prepared for any kind of emergency too. "The NHRI supports the Department of Health policies to fight disease by producing vaccines in case of an emergency. We would take approximately two months to prepare a vaccine from the H7N9 virus strain, another six months for mass production of the vaccine by domestic vaccine manufacturers, and then it will go through the final market authorization by the health authorities," said Su Ih-jen, director, National Institute of Infectious Diseases and Vaccinology, NHRI, talking about Taiwan's preparedness to combat H7N9. Further the first batch of three-to-five million doses of the vaccine produced would be provided to the disease control workers, healthcare officials and poultry farmers.

The WHO has recommended that all countries stock up enough pandemic influenza antiviral medicines like Tamiflu by Roche and Relenza by GlazoSmithKline. "While we continue to do much of the preparation work, there is no decision yet as to how far to push forward the development and whether we need to make the vaccine. But if we do need to make the vaccine, it cannot be done overnight. It typically takes four-to-six months for companies to produce the first doses of vaccine and then it takes some more time for production to take place," a senior WHO official explained to BioSpectrum.

Learning the hard way

This outbreak has brought back horrific flashbacks of swine flu or H1N1 pandemic of 2009 that revealed the unpreparedness of the industry to handle an epidemic that had the potential to turn into a pandemic. The first reported cases of H1N1 came in August 2009 and the industry had the vaccines ready for commercial use by October, by which time the economic losses were humungous. This time around however, it took the industry majors two months to begin the process of preparation of the vaccine.

The Global Influenza Surveillance and Response System (GISRS) formed by the World Health Organization (WHO) in 2009 to handle the crisis, currently operates 150 laboratories in 111 countries. The WHO Collaborating Center in Beijing, China, jumped into action immediately after the Avian Influenza A (H7N9) virus was detected. The viruses were immediately isolated and shipped to all the Essential Regulatory Laboratories of GISRS and other WHO Collaborating Centers for tests, assessment and candidate vaccine virus development for pandemic preparedness. Classical re-assortment and reverse genetics, the technologies that were developed during the 2009 swine flu pandemic, were bettered and are now being used to develop high-growth re-assortants that would help in vaccine development and production.

So far, the WHO has classified this outbreak level as class III epidemic (transmission between animals and limited transmission between animals and humans) and unless the level is raised to four (transmission between humans), vaccine manufacturing will not commence. Many of the big players in the influenza vaccine manufacturing domain have nonetheless began screening the right seed strains in order to eventually produce the vaccine.

The Biomedical Advanced Research and Development Authority (BARDA) stated that the industry seems to have learnt from their mistakes made in 2009 and seems to be much better prepared this time around. "I think we are in a much better place than we were before the pandemic of 2009. Our ongoing initiatives are starting to provide results," said Dr Robin Robinson, BARDA, at the WHO global conference earlier this month.