

## India's Swine Flu Bravado

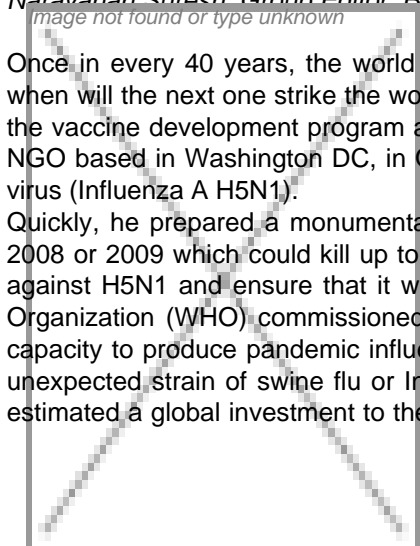
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*An unprepared health system is endangering the nation's future and the tardy manner in which the country's health authorities responded to advance warning from global experts about the impending pandemic is nothing but callousness towards the citizens*

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Once in every 40 years, the world has witnessed a pandemic influenza occurrence and the last one occurred in 1968. So when will the next one strike the world? This was the question troubling a quiet and unassuming, Dr John Boslego, director of the vaccine development program at the Program for Appropriate Technology in Health (PATH), a big but not-so-well known NGO based in Washington DC, in October 2007. He was actually worried about the spread of the bird flu or avian influenza virus (Influenza A H5N1).

Quickly, he prepared a monumental report that mapped the global scenario in the case of such an outbreak happening in 2008 or 2009 which could kill up to 100 million people worldwide. He was worried more about the development of a vaccine against H5N1 and ensure that it was available in most of the developing countries. Based on his report, the World Health Organization (WHO) commissioned global consultants, McKinsey and prepared a business plan in February 2008 to build capacity to produce pandemic influenza vaccines in all corners of the world. India and the world, now ravaged by the totally unexpected strain of swine flu or Influenza A H1N1 virus should thank Dr Boslego for his foresight and wisdom. For, WHO estimated a global investment to the tune of \$3 billion (Rs 15,000 crore) to set up manufacturing capacities to quickly make a

vaccine against any pandemic influenza within six months of it being declared as “pandemic” (global spread) and make available over 13 billion doses of the vaccine.

More than two-thirds of the 32 companies with the capability to make quality influenza vaccines were located in Europe and the US. Past experience indicated that in the event of a global epidemic, the countries where these vaccine manufacturing units were located would lay the first claim on the products. Very little will be left for the bulk of the global population who will need it the most in an emergency situation. So WHO selected six companies —Serum Institute of India, Pune, Birmex (Mexico), Bio Farma (Indonesia), Government Pharmaceutical Organization (Thailand), Vabiotech (Vietnam) and Butantan, Brazil—to equip them with the expertise, technical assistance and production capability to develop and manufacture any new pandemic influenza vaccine. It will take approximately six months from the time seed virus samples of a new influenza strain is handed over to these companies to develop, test and commercially make available the first set of vaccine.

WHO's preparations have come in handy in the current situation. The seed virus of H1N1, isolated from the first set of patients in Mexico and California were quickly sent to the newly identified companies too along with the supplies to the vaccine makers in Europe and the US. Two other Indian companies, Panacea Biotec (Delhi) and Bharat Biotech (Hyderabad) too have got the seed virus from WHO.

Animal trials of the vaccine have started in India and in Australia, China, Europe and the US small scale human trials too have begun. Most probably, the first set of vaccines will be available in December.

Even if vaccines against H1N1 virus are available in India and the world, it is not necessary that Indians will get it quickly. It is here the folly or the negligence of Indian government comes in. The government did not wake up to the danger of an impending influenza epidemic in 2008 even though many health ministry officials have been making frequent visits to the WHO headquarters in Geneva. There is no strategic plan with the health ministry to tackle if the H1N1 virus infects 350 to 400 million people, as predicted by Health Minister Ghulam Nabi Azad in early August. Even a single percent mortality rate implies that 3.5 to 4 million Indians could die of the disease in the next two years.

The Health Minister has talked about importing the swine flu vaccine from foreign companies. Most sensible governments abroad have already placed orders for more than 300 million doses of the vaccine from just one company, GSK. There is no word from Indian government about any vaccine orders being placed. Even the three Indian vaccine companies have so far got only oral assurances on vaccine procurement by the government.

Firm buyer commitments are essential for vaccine companies because current regulations do not permit open market sale of such essential products. Till recently our government had monopolized Tamiflu, the only medicine which can treat H1N1 infection now, keeping all the national stocks with it. The Tamiflu stocks have depleted even as Indian companies are exporting these to neighbouring countries. The vaccine against H1N1 will have to be stockpiled by public agencies as it will be effective only for a year. If not used within 12 months, the stocks will have to be destroyed and fresh supplies arranged for emergency use.

This was the reason why most of the western governments placed advanced orders worth \$ 2 billion for the pandemic influenza (H5N1) vaccine soon after the WHO report in early 2008 with the top vaccine manufacturers. So these vaccine manufacturers in Europe and USA have had a head start over their counterparts in developing nations like India. Australia has ordered 42 million doses of the H1N1 vaccine to the country's only manufacturer, CSL Ltd, to vaccinate each of her 21 million citizens. The Beijing government has ordered 10 million doses of the vaccine from the country leading vaccine maker, Sinovac.

Time is running out for our country. There are several technological challenges in increasing the quantity of the H1N1 vaccine when it is approved by the regulators for large scale use. The influenza virus grows very well in chicken eggs and alternate technologies to make it such as the cell culture method and recombinant DNA technology are untested.

There are only four companies in the world which produce the special fertile eggs, called Specific Pathogen Free (SPF) eggs, which will be used to make the H1N1 vaccine. Two of these manufacturers are in the USA and the third one is in Germany. The fourth one, Venkateshwara Hatcheries, the only Asian company with the expertise to make SPF eggs, is in Pune. The capacity to produce these SPF eggs, each of which costs more than Rs 30-50 is limited. In a year, the company may be able to spare only 30 to 40 million eggs for this purpose to human vaccine makers. These eggs are used mostly in the manufacture of poultry and cattle vaccine. Each egg could be used to make just one dose of the influenza vaccine. Due to this capacity constraint within the country, it may be possible to vaccinate less than 10 percent of Indians in a year. India will be lucky if other nations spare their vaccine stocks and rush to our aid if the need arises.

Of course it may be too much to expect India's health ministry officials to make strategic plans to stock pile essential vaccines in larger public interest. The ministry has been callous in neglecting the country's future citizens, born in the last two to three years. Only 80 percent of 27 million new born children born in each of the last two years got their first shots of essential vaccines under the National Immunization Programmes. The ministry could not find more than Rs 65 crore to buy these essential vaccines from the manufacturers in the country and created a shortage. The harmful effects of not providing essential vaccination to more than 10 million children in the last two years will be evident in the next few years when infections like H1N1 spread across the country rapidly.

Sitting far away from the H1N1 cities of India, Dr Boslego, had the foresight to warn the humanity against the impending danger. India's policy makers did not listen to him for nearly two years. It is not too late even now. Instead of patting itself on the back for the limited number of deaths caused by the swine flu virus so far, the government will do the nation a big service if it cranks up its procurement machinery and make available resources and announce its commitment to safeguard the

health of its citizens immediately.