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WHO initiative to increase global and equitable access to influenza vaccine in the event of a pandemic: Supporting developing country production capacity through technology transfer

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ABSTRACT

Should a highly pathogenic avian influenza virus, such as the H5N1 virus type currently circulating in birds, become transmissible among humans, an effective vaccine, rapidly available in vast quantities, would be the best tool to prevent high case-fatality and the breakdown of health and social services. The number of vaccine doses that could be produced on demand has risen sharply over the last few years; however, it is still alarmingly short of the 13 billion doses that would be needed if two doses were required to protect fully the world's population. Most developing countries would be last in the queue to benefit from a pandemic vaccine. The World Health Organization, together with governments, the pharmaceutical industry and other stakeholders, has been implementing the global pandemic influenza action plan to increase vaccine supply since 2006. Building capacity in developing countries to manufacture influenza vaccine is an integral part of this plan, as well as research and development into more efficacious technologies, e.g. those that allow significant dose-sparing. To this end, the influenza vaccine technology transfer initiative was launched in 2007 and, to date, vaccine manufacturers in 11 developing countries have received grants to acquire the capacity to produce inactivated or live attenuated influenza vaccine for their populations. In addition, a centralized 'hub' has been established to facilitate training in the new technologies for scientists and regulators in the countries. This supplement of *Vaccine* is devoted to showcasing the interim results of the WHO initiative and the impressive progress made by the developing country manufacturers.

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1. Introduction

The world has been on its guard against avian influenza (A)H5N1 ever since 1997, when a highly pathogenic virus crossed the species barrier to affect humans working in close contact with infected poultry in the Hong Kong Special Administrative Region, People's Republic of China. Between February 2003 and December 2010, the World Health Organization (WHO) received reports of 516 human H5N1 influenza cases, of whom 306 died, representing a case-fatality rate of over 59%. This, and the threat of an imminent, severe pandemic led the Fifty-eighth World Health Assembly in 2005 (resolution WHA58.5) to urge countries to strengthen their pan-

demical influenza preparedness and response. The WHO Secretariat was requested to seek solutions to increase global capacity to produce epidemic and pandemic influenza vaccines, and to encourage research and development (R&D) into new and improved vaccines, particularly those that required a lower antigen content per dose. This recommendation was based on awareness that containment measures, although critical, may delay but cannot alone prevent the spread of a deadly influenza virus.

In November 2005, WHO convened the first of a series of meetings on the development and clinical evaluation of influenza vaccines targeting viral strains with pandemic potential [1], during which researchers, manufacturers and regulators review safety and efficacy standards, antigen-sparing strategies, and priority research needs. These meetings complement those organized by WHO since 2004 on the development of influenza vaccines that induce broad spectrum and long-lasting immune responses. It was considered that vaccines with these characteristics could protect against anti-

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genic variants within a subtype and, at least partially, against infection by novel viruses with the potential to cause a pandemic.

2. Global action plan to increase vaccine supply

In order to address a central concern of the World Health Assembly – reducing the anticipated gap between influenza vaccine supply and demand in a pandemic situation – WHO organized a landmark consultation to identify the most promising approaches to enable the immunization of the world's 6.7 billion population within the shortest possible time. Thus, in May 2006, the global pandemic influenza action plan to increase vaccine supply (GAP) [2] was agreed upon by a broad range of stakeholders representing policy makers, national immunization programmes, regulatory authorities, vaccine manufacturers and the research community. To achieve the overarching goal, three mutually reinforcing strategies were considered urgent and essential: the promotion of seasonal vaccination programmes to increase market demand and drive production capacity; the expansion of manufacturing capability, particularly in developing countries; and enhanced influenza vaccine R&D.

In 2006, global production capacity for seasonal influenza vaccine was estimated at 350 million doses. Although annual capacity had reached nearly 900 million doses in 2009 [3], this still falls alarmingly short of 13.4 billion pandemic doses, should two doses be required to elicit immunity in the entire world population within six months of a pandemic alert. Moreover, in 2006, 90% of influenza vaccine production was located in nine countries (largely in Europe and North America) that represented only 10% of the global population. Other countries, notably those in Africa, the Middle East and Asia, could witness a staggering death toll and a severe strain on their health services while waiting for producing countries and regions to have vaccinated their own populations.

In May 2007, the Sixtieth World Health Assembly, noting the objectives and strategies of the GAP, requested the Secretariat in resolution WHA60.28 to seek ways to ensure the equitable sharing of benefits of influenza vaccine R&D, including the development of capacity for influenza vaccine production in developing countries. Indeed, domestic or regional production was considered one of the most effective strategies for vulnerable countries and regions to have access to an influenza vaccine in the event of a pandemic. The general consensus to increase global access to drugs, vaccines and diagnostics was significantly promoted through adoption of the global strategy and plan of action on public health, innovation and intellectual property (GSPA-PHI) by the Sixty-first World Health Assembly in May 2008 (resolution WHA61.21). Two elements highlighted by the GSPA-PHI were the need to build and improve capacity in developing countries, and to facilitate the transfer of health-related technologies. The GSPA-PHI thus provided further legitimacy to the WHO strategy of enhancing influenza vaccine production through technology transfer to developing countries.

Progress by WHO, its global partners and developing countries towards this strategy is the focus of this special edition of *Vaccine*.

3. WHO influenza vaccine technology transfer initiative

In 2007, WHO embarked on an ambitious initiative to increase the capacity for influenza vaccine production in developing countries. To date, more than US\$ 25 million have been awarded to 11 developing country manufacturers to establish or enhance this capacity. Grants have also enabled the establishment of a centre of excellence for training and transfer of influenza vaccine production technologies to new manufacturers. In addition, WHO has negotiated a non-exclusive licence for a live attenuated influenza vaccine (LAIV) technology. A summary of the rationale behind the choice of

the technologies and the selection process for the awards under the aegis of the WHO influenza vaccine technology transfer initiative is provided in this Section.

3.1. Selection of technologies

In order to assist developing country vaccine manufacturers to identify technologies most suited to their needs, WHO commissioned in 2006 a review of the technologies used to produce the currently registered influenza vaccines [4]. The review considered whole-virion, split and subunit inactivated, as well as live attenuated vaccines, produced either in eggs or cell culture. It also considered the capital investment required to establish a manufacturing facility, the time needed for product approval, and the relative cost of vaccine produced by each method. The review concluded that the egg-based inactivated influenza vaccine (IIV) production process was potentially the easiest to establish as it is used to produce more than 90% of vaccines available on the market and presents few unknowns in the path to regulatory approval. In contrast, tissue-culture based production of IIV requires much greater financial investment and, at the time of the review, faced numerous regulatory questions.

For pandemic surge capacity, egg-based LAIV requires smaller capital investment than IIV and offers significantly higher yield, faster quality control and release and, importantly, needle-free administration. This made LAIV an attractive option, particularly for developing countries with very large populations and limited numbers of health-care workers able to administer injectable IIV in a short period of time. However, while the LAIV manufacturing process is simple and potentially easier to transfer to developing countries than IIV, the production and distribution of LAIV requires a licence agreement with one of the two technology owners (see Section 3.3 below).

The review did not evaluate in detail upstream vaccine technologies such as recombinant antigens, viral vector- or DNA-based vaccines. Although promising, none of these technologies were licensed at that time, and it was therefore premature for WHO to recommend them to developing countries. The review did, however, point out that the addition of adjuvants, particularly oil-in-water emulsions, to IIV permitted significant dose reduction and could therefore be very useful for surge production in the event of a pandemic.

3.2. Selection of manufacturers

Following a first public call for proposals via the WHO web site in 2007, six developing country vaccine manufacturers were awarded grants (out of nine who applied) to establish or expand influenza vaccine manufacturing capacity, and a further five were selected subsequent to a second call in 2009. The 11 vaccine manufacturers (Table 1) have received grants of between US\$ 0.5–4.27 million. All proposals were evaluated against mandatory criteria, technical merit, public health value and potential domestic and regional impact by an independent external Technical Advisory Group. In addition, each manufacturer was required to demonstrate government support for its proposal – a critical element to ensuring that manufacturing plans are in line with immunization plans.

One mandatory criterion was that a manufacturer was producing at least one human vaccine approved by the national regulatory agency. Given the complexity of influenza vaccine production, this helped ensure the transfer of technology to experienced manufacturers, and contributed to the success of the project. However, the criterion eliminated emerging manufacturers that were keen to establish local influenza vaccine production but had not (yet) registered a vaccine for human use. In order to address the urgent need for regions such as sub-Saharan Africa to be able to produce

Table 1
Developing country vaccine manufacturers selected by WHO in 2007 and 2009.

Country	Manufacturer	Public or private	2007 grantee (1st round)	2009 grantee (2nd round)
Brazil	Instituto Butantan	Public	X	
Egypt	Vacsera	Public		X
India	Serum Institute of India	Private	X	
Indonesia	Bio Farma	Public	X	
Iran	Razi Institute	Public		X
Mexico	Birmex	Public	X	
Republic of Korea	Green Cross Corporation	Private		X
Romania	Cantacuzino Institute	Public		X
Serbia	Torlak	Public		X
Thailand	Government Pharmaceutical Organization	Public	X	
Viet Nam	Institute of Vaccines and Medical Biologicals	Public	X	

pandemic influenza vaccine, future calls may see modified criteria to take this into account.

3.3. Intellectual property and know-how considerations

To complement its review of production technologies, WHO undertook an analysis of intellectual property (IP) issues related to each manufacturing process to identify potential IP barriers and areas where new manufacturers would have to seek licences [5]. The report noted that it was not patents, but access to technical know-how and regulatory dossiers that potentially constituted significant barriers, even for conventional egg-derived influenza vaccines. Thus, partnerships with technology holders were sought to ensure the successful and rapid establishment of production capacity.

Similarly, there are no significant patent barriers to produce live attenuated influenza vaccines, which have been widely used in Russia and the former Union of Soviet Socialist Republics for the last thirty years. Nonetheless, access to strains with a well documented safety and efficacy profile, and to corresponding regulatory documentation, would avoid the lengthy and expensive process of deriving a new LAIV through *de novo* attenuation of pathogenic virus strains. To facilitate access to such attenuated strains, WHO acquired from Nobilon (now Merck) a licence on the technology developed by the Institute of Experimental Medicine in St Petersburg, Russia. This royalty-free licence to develop, manufacture and sell to the public sector both seasonal and pandemic egg-derived LAIV allowed WHO to provide sub-licences to manufacturers in developing countries (see article by Rudenko et al. [8]).

The report also noted that no IP barriers existed in developing countries for an oil-in-water emulsion that permits considerable dose-reduction with IIV, since patents had not been filed in these areas of the world. This opened the possibility for developing coun-

try vaccine manufacturers to produce and use adjuvants to expand IIV capacity in the event of a pandemic. Again, know-how was identified as a major hurdle.

4. Technology transfer

Effective technology transfer is arguably the most effective route for developing countries to secure sustainable access to quality influenza vaccine production technology. As pointed out above, technology transfer from an entity that has a registered product is the most effective, as this reduces risk to the recipient and facilitates rapid approval of the locally produced product. However, while most major vaccine manufacturers have undertaken technology transfer for early childhood vaccines, few have been willing to transfer their influenza vaccine technology. During the initial phase of the WHO influenza vaccine technology transfer initiative, only three of the six grantees were successful in securing such technology transfer partnerships. For those unable to negotiate agreements, the next best approach was to hire the services of the few independent consultants with experience of large-scale influenza vaccine production, to assist the new manufacturers in setting up the production processes. However, these consultants rapidly found themselves thinly spread, facing different strategies for vaccine production and varying levels of capacity to absorb the technologies. WHO therefore decided to facilitate the creation of an influenza vaccine technology 'hub' – a relatively novel concept for vaccines. Where previous technology transfer had been bilateral between a technology donor and single recipient, the hub model entails the establishment of a complete manufacturing process and enables multiple recipients to receive 'turnkey' technology transfer. A schematic comparison of the classic bilateral model and the hub model for technology transfer is provided in Table 2.

Table 2
Comparison of models for technology transfer.

Type	Schematic diagram	Advantages	Drawbacks
Bilateral		Ideal for win-win situations where donor and recipient benefit.	Not readily feasible in cases where there is limited financial benefit for donor.
Hub		Ideal when multiple recipients need the same technology.	Not readily feasible where multiple intellectual property barriers exist or where know-how is not easily available.

A number of conditions needed to be met for the creation of a successful influenza vaccine technology transfer hub [6]. The first was that the technology had to be free of intellectual property barriers, both at the hub site and in recipient countries. Secondly, the hub must have manufacturing and quality control experience and infrastructure in line with WHO requirements. In addition, there should be no competing interest of the hub facility in the commercial markets of the recipients. Lastly, financial support must be available to see the hub through the technology development phase, with the premise that sustainability would be ensured at a later stage through financial contributions from existing and new technology recipients.

Several entities, including private contract research organizations, public vaccine development centres, and public or private vaccine manufacturers, were envisaged as potential candidates to serve the role of a hub. An open call for proposals published on the WHO web site resulted in the selection in 2008 of the Netherlands Vaccine Institute (NVI) as the technology hub for influenza vaccines. NVI was a Dutch governmental vaccine manufacturer – although not in the area of influenza – with a successful record in transferring technology (see article by Hendriks et al. [9]).

Likewise, WHO facilitated the establishment in 2010 of a vaccine formulation centre of excellence at the University of Lausanne, Switzerland where the procedures for producing non-proprietary oil-in-water emulsions are being established for transfer to developing countries (see article by Collin and Dubois [10]). Establishing the centre in Switzerland was partly influenced by the fact that a relevant patent on submicron oil-in-water emulsions had been revoked in Europe. While the production of oil-in-water emulsions is not technically difficult and is well described in specialized literature, numerous parameters make it more effective to establish a centralized hub than to assist separate manufacturers to acquire the same technology. These range from procurement of raw materials for the emulsion, selection of the appropriate manufacturing equipment, and procedures for characterization and release of the adjuvant.

A technology transfer initiative using a concept similar to the adjuvant hub model is the 'Enabling Platform' [7] used by PATH to facilitate the transfer of rotavirus vaccine technology. In this type of upstream technology transfer, the production of reagents, quality control testing and formulation development (enabling technologies and tools) take place at different sites and serve multiple recipients.

5. Interim results of the initiative

A key measurable outcome of the initiative is the increased capacity of the new manufacturers to contribute influenza vaccine to their country and to the developing world in general. This is being assessed by comparing the number of new doses of trivalent seasonal influenza vaccine produced at the WHO grantee manufacturing sites against the 2006 baseline production. A survey was conducted in July 2010 among all 11 developing country vaccine manufacturers receiving grants from WHO. The questionnaire requested data on current seasonal influenza vaccine requirements and target groups in the country, as well as types of vaccine to be produced, including pandemic vaccine, production timeline, current production, maximum capacity, and forecasted capacity by 2015. All manufacturers responded to the survey, the results of which are summarized below.

Manufacturers in six countries (55%) reported that seasonal influenza vaccination was currently part of their national immunization programme. Two of the remaining five countries (18%) indicated the intent of their government to introduce influenza vaccination into the national immunization programme in the next five years.

Three manufacturers (27%) reported having already produced and distributed seasonal influenza vaccine in their countries. The others indicated that they would commence commercial-scale vaccine production between 2010 and 2012. The total number of influenza vaccine doses produced for the 2010 seasonal epidemic was reported as 12 million, with more than 215 million doses forecasted to be produced annually in 2015 (Table 3). Approximately half of these doses will be the inactivated formulation and the other half will be LAIV. Three manufacturers produced H1N1 pandemic vaccine in 2009 and 2010 for their country's use, at an aggregate total of 33 million doses as at 31 December 2010.

Finally, the survey results indicate that 9 of the 11 manufacturers (82%) will be able to meet the demand for seasonal influenza vaccine in their country by 2015 (two countries do not plan to introduce seasonal influenza in their vaccination programme by this date) (Fig. 1).

The survey also estimated the investment cost in US dollars per dose of influenza vaccine to be produced in 2015 by manufacturer, based on expenditure to date, future financial needs and number of forecasted annual doses (Fig. 2). As predicted, tissue-culture based technology requires significant capital investment, whereas egg-derived LAIV requires the least investment.

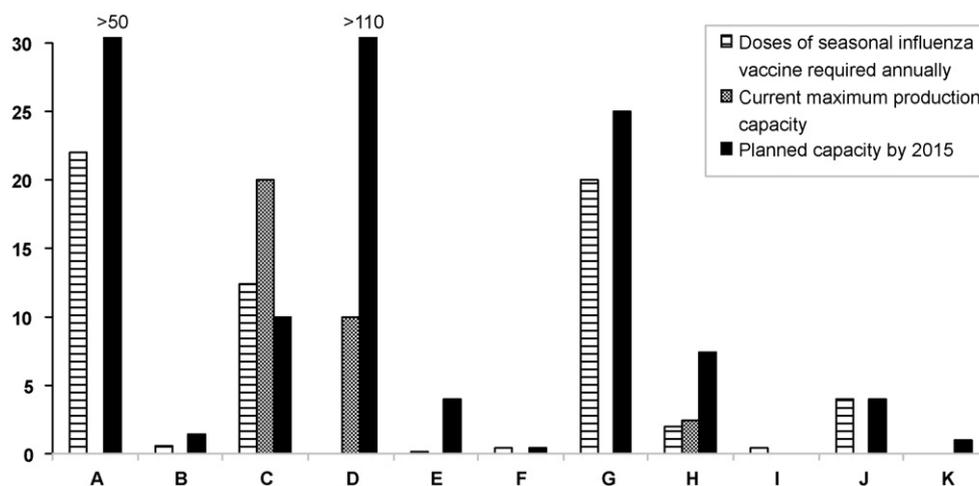


Fig. 1. Annual influenza vaccine requirements, current maximum production and forecasted capacity by 2015, in million doses, by manufacturer.

Table 3
New influenza vaccine production capacity (in million doses).

Company	Seasonal influenza vaccine required annually by national programme	Current production and capacity			Planned registration (year)	Forecasted annual production in 2015	Type of vaccine
		Seasonal influenza vaccine produced annually	H1N1 pandemic vaccine produced by 31 March 2010	Maximum production capacity (seasonal)			
A	22.0	0	0	0	2011	50	Inactivated split vaccine
B	0.55	0	0	0	>2012	1.5	Inactivated whole virion vaccine
C	12.5	10	26	20	Already registered	10	Inactivated split vaccine
D	0	0	0	10	2010	110	Inactivated split and LAIV
E	0.20	0	0	0	2011	4	Inactivated whole virion
F	0.40	0	0	0	>2012	0.50	Inactivated whole virion
G	20	0	0	0	2012	25	Inactivated split vaccine
H	2	2	3	2.5	Already registered	7.5	Inactivated split vaccine
I	0.40	0	0	0	2011	2	Inactivated whole virion
J	4	0	1.5	0	2012	4	Sub unit inactivated and LAIV
K	0	0	0.005	0	2012	1	Inactivated whole virion
Total	62.05	12	30.505	32.5		215.5	

Although eggs can present a potential barrier to manufacture in resource-poor settings (e.g. importation of eggs and/or maintenance of hen flocks), the affordability of the final product is of prime importance and egg-based production appears to be the cheapest.

One parameter not visible in Fig. 2 is how these costs would be affected by the use of adjuvants as these could multiply the number of pandemic IIV doses by at least 4-fold, for minimal capital investment. One of the WHO grantee manufacturers embarked on a programme for the transfer of an oil-in-water adjuvant technology from the Vaccine Formulation Laboratory in December 2010.

6. Discussion

Supporting selected developing countries to establish or expand pandemic influenza production capacity is not sufficient to ensure that all developing countries have access to pandemic vaccine. Moreover, it is not possible, nor desirable to establish influenza vaccine production in each and every country. For this reason, WHO grants to manufacturers are contingent upon their agreement to sell at an affordable price 10% of their pandemic vaccine production

to United Nations agencies such as WHO and UNICEF, if needed in a pandemic event, for distribution to developing countries without domestic production.

Other issues require priority attention if the overall goal is to be achieved. The concomitant training and support for regulatory authorities in developing countries, for example, is needed to ensure that influenza vaccines produced there can be registered and licensed without unnecessary delays.

Another issue of concern is the remaining geographical imbalance in global influenza vaccine production capacity, and thus access to pandemic influenza vaccine, particularly in countries in sub-Saharan Africa. A third call for proposals to establish influenza vaccine production capacity in developing countries will target such regions.

In response to growing interest by the global health community in the development of local production to improve access to medicines, WHO undertook an analysis of vaccine-related technology transfer projects over the last two decades. The analysis identified over 100 such transfers to developing countries (principally to Brazil, China and India), the majority of which resulted in increased local production and use of the vaccine. A consultation

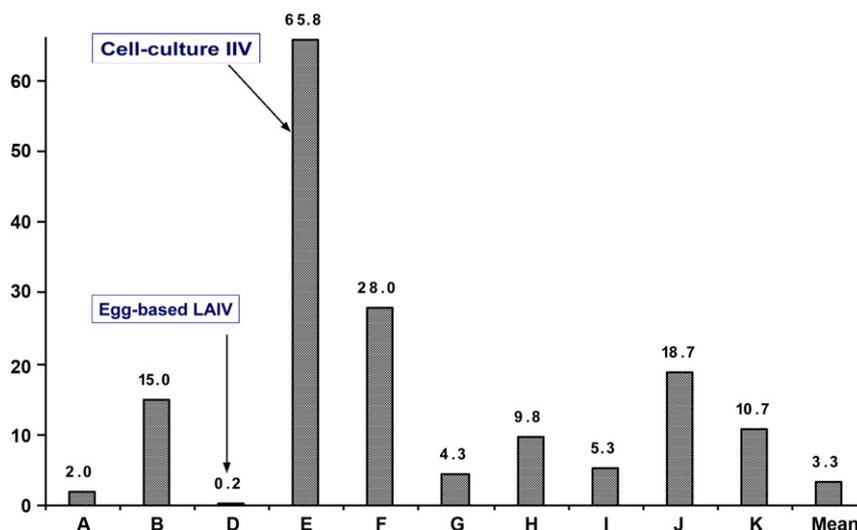


Fig. 2. Average investment cost per dose in US\$ of influenza vaccine to be produced by 10 of the 11 manufacturers in 2015, based on expenditure to date, future financial needs and number of forecasted annual doses.

held in December 2010 identified the following considerations for technology transfer to developing countries.

Firstly, although local production does not necessarily mean lower prices, it should be seen as a strategic investment in health. Secondly, the dynamics of technology transfer are evolving: while the vast majority of the above-mentioned vaccine technology transfers were bilateral, multinational vaccine manufacturers are increasingly establishing their own plants in countries with emerging economies. In order to compete with these research-driven manufacturers, new manufacturers will need to invest in R&D, and their governments in an enabling environment to assure future opportunities for technology transfer. Thirdly, increased local vaccine production can lead to excess supply over demand. In the 1980s, this situation resulted in several vaccine manufacturers leaving the field and a transient shortage of some vaccines. In the case of seasonal influenza vaccine, the advantages in terms of health security of establishing more geographically balanced production capacity for pandemic vaccine are considered to outweigh the risks posed by excess capacity.

The consultation concluded that, given limited production capacity, technology transfer – is cost-effective and the hub model where appropriate – is cost-effective and should be considered for new vaccines such as conjugate pneumococcal or dengue vaccines in order to ensure universal access to immunization in developing countries.

7. Conclusion

In the last decade, the threat of highly pathogenic avian influenza viruses to populations, health systems and socio-economic infrastructures compelled governments across the world to increase their preparedness for the next such emergency. Public health agencies, research institutions, the pharmaceutical industry and major development partners are among those that responded rapidly to the alarm. WHO Member States reinforced the importance of health security in policies and guidelines such as the updated International Health Regulations (2005), and through innovative strategies such as the WHO initiative to increase influenza vaccine production capacity in developing countries.

Overall progress of the 11 grantee vaccine manufacturers towards their specific objectives has been impressive (results of the six manufacturers awarded grants in the first round of proposals are detailed in their respective articles published in this supplement). Within a short period of time, three manufacturers have registered a seasonal or pandemic vaccine with their national regulatory authorities, even though two of these had no prior knowledge of influenza vaccine production. Several more have reached the late stages of clinical evaluation.

Supported by a solid monitoring and evaluation programme (see article by Francis and Grohmann), WHO has contributed to increased global influenza vaccine production capacity for

more equitable access to a life-saving vaccine during a pandemic. Although the severity of the 2009 H1N1 pandemic was characterized as moderate, there is no room for complacency, as increasing numbers of human cases of H5N1 influenza are being reported in several countries. Support should therefore be maintained to the current grantees and expanded to new manufacturers to allow them to complete or initiate their technology transfer projects.

Disclaimer

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