Epidemic Preparedness: National Security for Thailand

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- Situation in 2009
- Critical path for LAIV and IIV vaccines development
- Pandemic Preparedness

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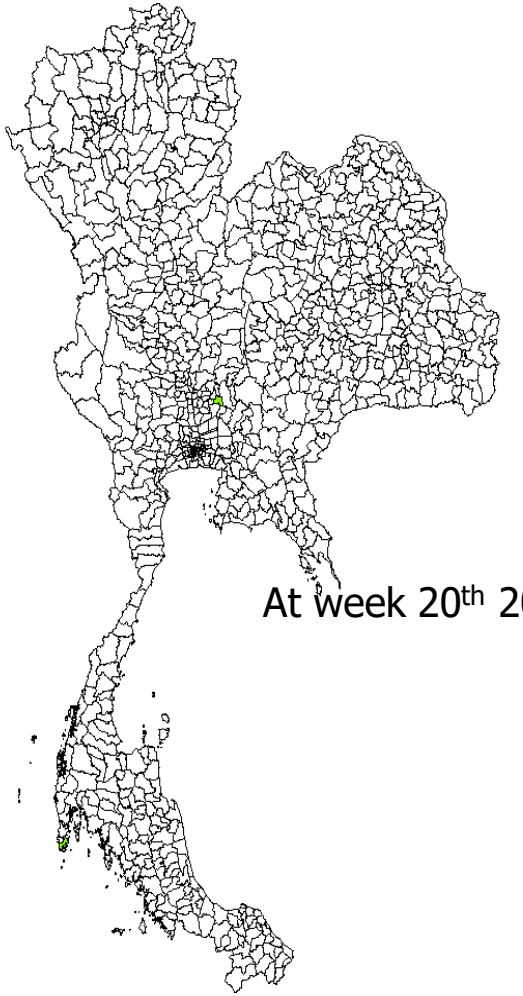
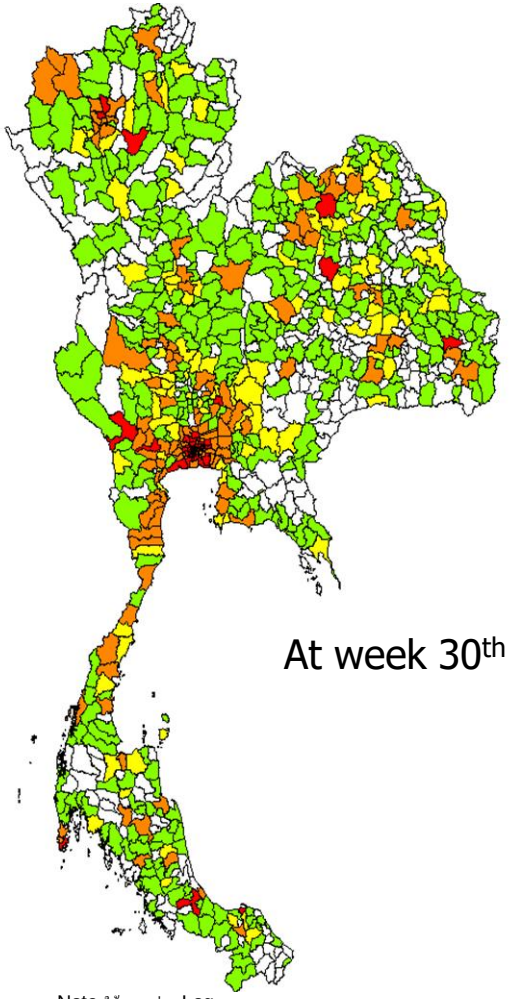
Distribution of confirmed influenza A (H1N1) cases by district in Thailand



At week 20th 2009 (Mid May)

สัญลักษณ์	จำนวนป่วย
	0
	1 - 5
	6 - 10
	11 - 50
	> 50



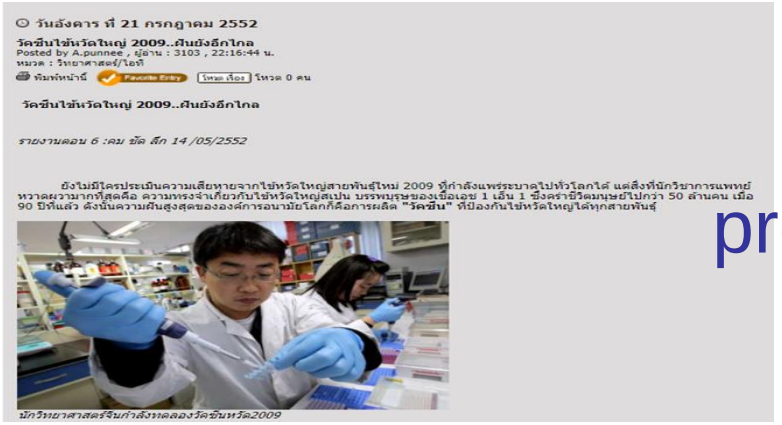
At week 30th 2009 (Late July)

Note ใช้มาตราส่วน Log

2009: Situation of Influenza Vaccine supply

- No domestic production of bulk influenza vaccine
- No experience of egg-based vaccine production before 2007
- Imported 2.1 million doses of seasonal influenza vaccine in 2010

GPO-MBP supplied approx. 800,000 doses, by formulating and filling of imported bulk seasonal influenza vaccine, the remainder 1.3 million doses was imported as finished products.



Influenza vaccine production : A far dream

Global Pandemic Influenza Action Plan to Increase Vaccine Supply by increasing production capacity

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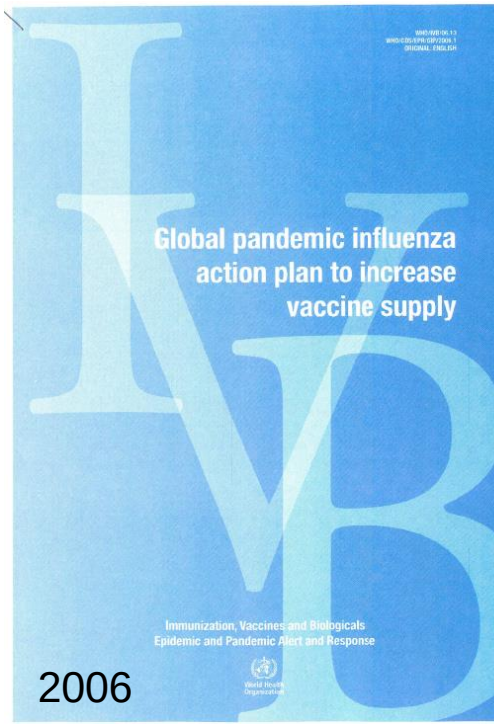
The objective of the Global Vaccine Action Plan is to increase the supply of a pandemic vaccine and thereby reduce the gap between the potential vaccine demand and supply anticipated during an influenza pandemic.



- improving production yields and immunogenicity for vaccines based on H5N1 influenza strains;
- building new production plants in both developing and industrialized countries;
- focusing on further development of adjuvanted vaccines with adjuvants widely used in licensed vaccines;
- expanding the production of live attenuated influenza vaccines (LAIV);
- evaluating the immunogenicity of inactivated whole-virus vaccines;
- evaluating the potential for delivering vaccines by alternative routes – for example, the intradermal route using needle-free delivery devices such as jet injectors.

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Thailand: The National Pandemic Preparedness Plans

- First (2005-2007)

"Support research and development of vaccines, antivirals……."

- Second (2008-2010)

"To set up a local industrial-scale manufacturing plant for pandemic influenza vaccine based on international standard with production of specific pathogen free (SPF) eggs to support the vaccine production processes"

"Personnel capacity to be able to do industrial-scale vaccine research and development processes"

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Development Plan

- LAIV H1N1 vaccine
- Avian H5N2 vaccine
- Seasonal inactivated influenza vaccine

Why start with LAIV: Potential advantages of LAIVs

- no down-stream processing required (harvested vaccine is simply packaged);
- High yield (20-50 doses of monovalent vaccine per an egg);
- Needle-free delivery (administration is via an intra-nasal spray), which may facilitate administration in resource-poor settings;
- Induction of broader immune responses including mucosal, systemic and cell-mediated responses (in contrast parenterally administered inactivated vaccines do not induce mucosal immunity);
- Able to induce cross-reactive immune responses;

History of LAIV Development in Thailand

- 2004 outbreak of H5N1 in Thailand
- 2005 Indonesia stop sending flu viruses to WHO
- 2006 Serious discussion on equitable sharing of benefits from sharing viruses
- 2007 WHO/HQ started supporting developing countries to build up capacity to produce Influenza vaccine in 6 countries, including Thailand

- May 2009 Sublicensing agreement on LAIV with WHO based on Russian Technology from IEM, St. Petersburg
- July 2009- received the H1N1 (2009) pre-Master seeds from Russia, through WHO support

- WHO sent experts to Thailand

- August 2009 -first PLAIV vaccine concentrate was harvested leading to
  first PLAIV clinical lot filled and tested

Initial obstacles for production

- Less yield, low dose than expected
- SPF eggs-imported
-German, US
-not available in Thailand
-Stabilizer?? And so____

Facility for GMP production of clinical trial lot certified by WHO

Pilot plant at Silapakorn U

Pulled in resources from both public and academic sectors

GPO-Mahidol U
Fac Science
Fac Medicine, Siriraj H
Fac Trop Med
: Vaccine Trial Centre

Stages
of
Vaccine R&D

Efficacy & Safety

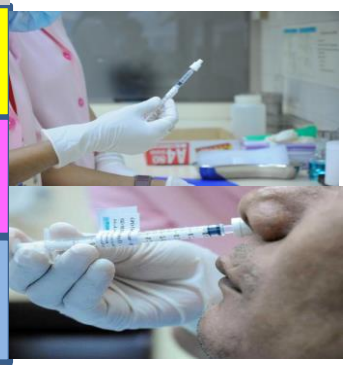
Safety & Immune responses

Clinical phase I
(Human Safety)

Safety ,Immunity, efficacy challenge in animal

Lab studies- Toxicity, stability, Pre-clinical studies

Manufacturing under GMP
CLINICAL LOT



Live attenuated Vaccine H1N1 LAIV

WHO FUND

2007 2008 2009 2010 2011 2012 2013 2014 2015 2016

1st WHO Grant US$ 1.996 million

2st WHO Grant US$ 2.064 million

Egg-based Monovalent PLAIV (H1N1)

Pre-clinical study

• Attenuation
• Challenge test in ferret

Clinical Trial Phase I

Clinical Trial Phase II

3rd/1 WHO Grant US$ 0.552 million

Vaccine approved (EUA) from TFDA for 18-49 years

Vaccine approved (EUA) from TFDA for 12-65 years

Thai gov-To establish an industrial-scale influenza vaccine production plant

Construction of industrial plant

Acknowledgement : GPO expresses its appreciation for the support of all partners, particularly, WHO, BRADA, USCDC, US and Japan Government, IEM, KAKETSUKEN, NIBSC, and Thai partners including. MOPH, TFDA, DMSC, SU and MU.

Vaccine 29S (2011) A29–A33

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Development of influenza vaccine production capacity by the Governmer Pharmaceutical Organization of Thailand: Addressing the threat of an influenza pandemic

Somchaiya Surichan[a], Ponthip Wirachwong[a], Wutichai Supachaturas[a], Kanchala Utid[a], Sompone Theerasurakarn[a], Pimsuk Langsanam[a], Pattharachai Lakornrach[a], Ladda Nitisaporn Chanpen Chansikkakorn[a], Wilak Vangkanonta[a], Ruangchai Kaweepornpoj[a], Kittisak Poopipatpol[a], Sit Thirapakpoomanunt[a,*], Somchai Srichainak[a], Witit Artavatkun[a], Vichai Chokevivat[a], Suwit Wibulpolprasert[b]

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ABSTRACT

In 2005, a year after highly pathogenic avian influenza outbreaks in Thailand, the Th issued a National Strategy Plan for Pandemic Influenza Preparedness, a major objective o domestic production of seasonal influenza vaccine. It was considered that sustained in production was the best guarantee of a pandemic vaccine in the event of a future pandem ment decided to provide funds to establish an industrial-scale influenza vaccine produc gave responsibility for this challenging project to the Government Pharmaceutical Orga In 2007, with support from the World Health Organization (WHO), the GPO started to dev trivalent inactivated influenza vaccine (IIV) in a renovated pilot plant. In early 2009, du year of the project, the GPO turned its attention to develop a pandemic live attenuated cine (PLAIV) against the influenza A (H1N1) virus. By December 2010, the H1N1 PLAIV h completed Phase II clinical trials and was awaiting registration approval from the Thai Administration (TFDA). The GPO has also started to develop an H5N2 PLAIV, which is ex clinical trials in January 2011. The next step in 2011 will be the development and clir of seasonal LAIV. To meet the needs of the national seasonal influenza vaccination progr aims to produce 2 million doses of trivalent IIV in 2012 and progressively increase product imum annual capacity of 10 million doses. This article relates how influenza vaccine prod was developed and how major challenges are being met in an expeditious manner, with s global commitment.

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Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Safety and immune responses following administration of H1N1 live attenuated influenza vaccine in Thais

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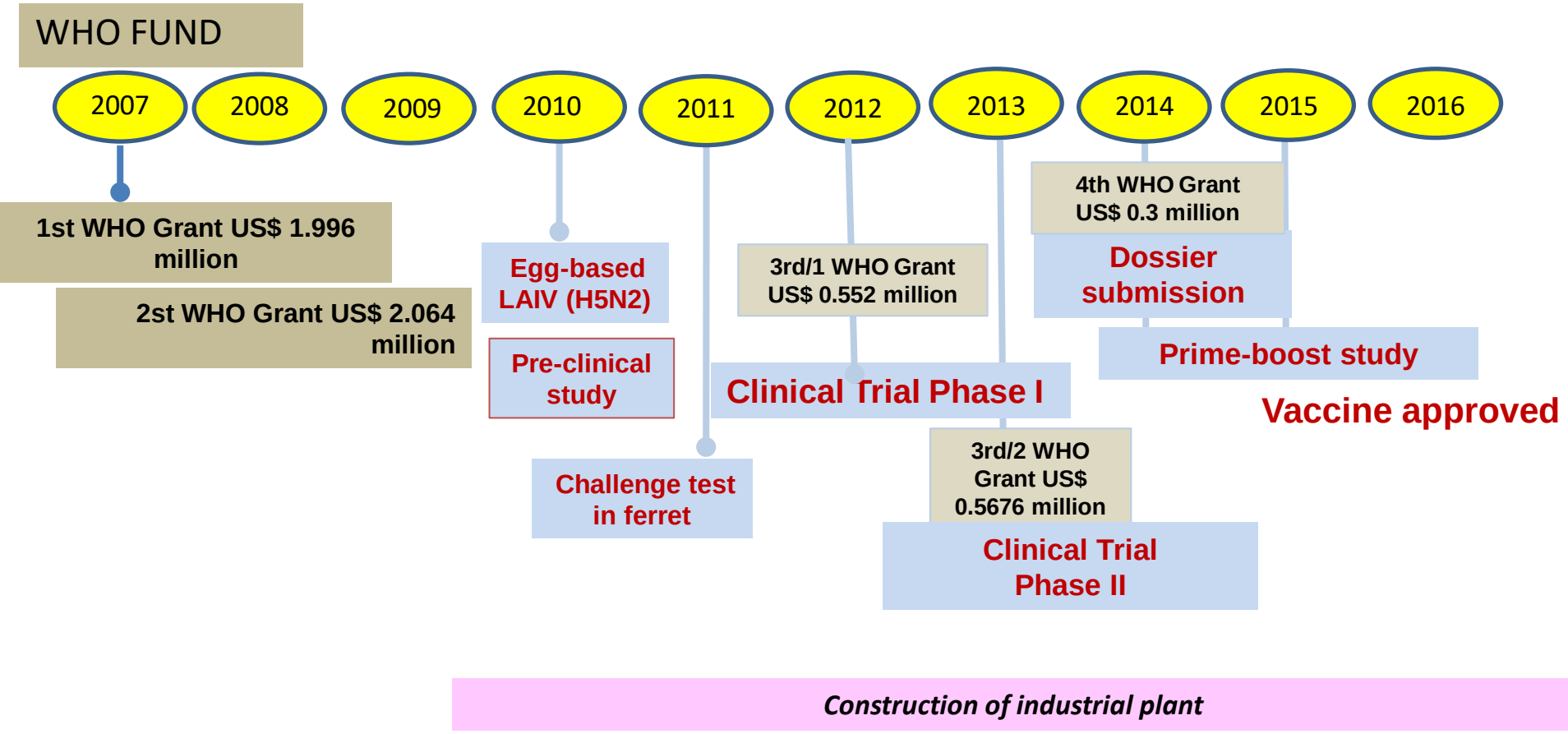
ABSTRACT

Background: Emergence and rapid spread of influenza H1N1 virus prompted health authorities to develop a safe and effective influenza vaccine for domestic use. The Thai Government Pharmaceutical Organization (GPO) with technical support from Russia through WHO had prepared a pandemic live attenuated vaccine (PLAIV) using *ca-ts* attenuated candidate strain A/17/CA/2009/38 (H1N1) for Thais.
Methods: Each participant received two doses of intranasal H1N1 vaccine or placebo 21 days apart. All were followed up at 7, 21, 42 and 60 days after first immunization. Blood was drawn for hemagglutination inhibition (HAI) assay from all participants at days 1, 21, 42, and 60 after first immunization. A subset of 40 participants aged 19–49 years was randomly selected for nasal washing at days 1, 21, 42, and 60 to assess IgA using direct enzyme-linked immunosorbent assay (ELISA) along with serum HAI and microneutralization (MN) assay determination.
Results: A total of 363 subjects aged 12–75 years were randomized into 2 groups (271 vaccinees:92 placebos). Almost all AEs were mild to moderate. Local reactions were stuffy nose (22.3%), runny nose (25.1%), scratchy throat (27.2%) and sore throat (19.3%). Systemic reactions included headache (21.7%), myalgia (13.8%), fatigue (16.8%) and postnasal drip (19.9%). On day 60, HAI seroconversion rates for vaccine:placebo group were 30.3:6.0 for ITT and 29.4:5.1 for PP analysis. Children showed highest seroconversion rate at 44, but it decreased to 39.4 when all 3 assays (HAI, MN assay and ELISA) from subgroup analysis were considered.
Conclusion: The vaccine candidate is safe. The use of more than one assay may be needed for evaluation of immune response because live attenuated vaccines could effectively induce different kinds of responses. Different individuals could also mount different kinds of immune response, even to the same antigen.

QA of HAI results by sending subset of samples to Us-CDC - the result was comparable

Live attenuated Vaccine H5 LAIV



Acknowledgement : GPO expresses its appreciation for the support of all partners, particularly, WHO, BRADA, USCDC, US and Japan Government, IEM, KAKETSUKEN, NIBSC, and Thai partners including. MOPH, TFDA, DMSC, SU and MU.

H5N2 LAIV : Only 14% of the participants received H5N2 LAIV had > 4 fold HAI antibodies

H5 Boosted Protocol

Objectives :

- aims to evaluate the effect of H5N2 LAIV priming on an inactivated sub unit H5N1 vaccine boost with prime-boost intervals of approximately 1 year.

Vaccine

- Subunit aluminium hydroxide adsorbed H5 influenza vaccine contain HA and NA protein from A/turkey/Turkey/1/05 (H5N1)

60 participants (40 V, 20 P phase II) have been enrolled and received 1 dose of H5 IIV (June30,14)

Serum antibody responses by influenza strain after inactivated H5N1 vaccine boosting between participants who had previously received vaccination (LAIV H5N2 vaccine; n=40) and participants who were naive (placebo; n=20) in the ITT population (1)

Source: Pitisuttithum P, et al. Lancet Infect Dis. 2017 Aug;17(8):833-842.

	Before vaccination		7 days after vaccination		28 days after vaccination		90 days after vaccination	
	Seroconversion	GMT	Seroconversion	GMT	Seroconversion	GMT	Seroconversion	GMT
Haemagglutination-inhibition antibodies								
A/turkey/Turkey/05/133								
Vaccinated	0/40 (0%; 0·00–0·00)	3·92 (3·24–4·75)	39/40 (98%; 92·66–100·00)	211·12 (134·45–331·52)	40/40 (100%; 100·00- 100·00)	566·89 (436·97–735·44)	39/40 (98%; 92·66–100·00)	245·11 (183·44–327·53)
Naive	0/20 (0%; 0·00–0·00)	2·59 (2·41–2·78)	3/20 (15%; 0·00–30·65)	3·66 (2·60–5·15)	14/20 (70%; 49·92–90·08)	25·49 (11·82–54·96)	15/20 (75%; 56·02–93·98)	26·39 (13·52–51·52)
p value	..	0·0019*	<0·0001†	<0·0001*	0·0008‡	<0·0001*	0·0031‡	<0·0001*
A/Thailand/1 (KAN-1)/04								
Vaccinated	0/40 0%; 0·00–0·00)	2·59 (2·46–2·72)	35/40 (88%; 77·25–97·75)	32·49 (22·01–47·96)	40/40 (100%; 100·00–100·00)	98·49 (75·44–128·58)	38/40 (95%; 88·25–100·00)	30·64 (22·93–40·94)
Naive	0/20 (0%; 0·00–0·00)	2·50 (··)	0/20 (0%; 0·00–0·00)	2·77 (2·46–3·12)	3/20 (15%; 0·00–30·65)	5·18 (2·90–9·25)	4/20 (20%; 2·47–37·53)	5·36 (3·48–8·26)
p value	..	0·3254*	<0·0001†	<0·0001*	<0·0001†	<0·0001*	<0·0001†	<0·0001*
A/Indonesia/5/2005 **clade 2.1.3.2**								
Vaccinated	0/40 (0%; 0·00–0·00)	2·59 (2·46–2·72)	38/40 (95%; 88·25–100·00)	68·45 (42·91–109·17)	39/40 (98%; 92·66–100·00)	187·00 (133·79–261·38)	38/40 (95%; 88·25–100·00)	59·14 (43·08–81·19)
Naive	0/20 (0%; 0·00–0·00)	2·68 (2·42–2·96)	2/20 (10%; 0·00–23·15)	4·51 (3·12–6·52)	14/20 (70%; 49·92–90·08)	9·01 (5·55–14·64)	12/20 (60%; 38·53–81·47)	8·71 (5·28–14·36)
p value	..	0·4792*	<0·0001†	<0·0001*	0·0042‡	<0·0001*	0·0004‡	<0·0001*
A/Laos/Nong Khai/1/2007 **clade 2.3.4**								
Vaccinated	0/40 (0%; 0·00–0·00)	2·50 (··)	35/40 (87%; 77·25–97·75)	33·06 (22·34–48·93)	38/40 (95%; 88·25–100·00)	105·56 (77·53–143·73)	37/40 (93%; 84·34–100·00)	35·95 (27·17–47·58)
Naive	0/20 (0%; 0·00–0·00)	2·50 (··)	0/20 (0%; 0·00–0·00)	2·59 (2·41–2·78)	3/20 (15%; 0·00–30·65)	4·35 (2·58–7·34)	4/20 (20%; 2·47–37·53)	4·51 (2·84–7·15)
p value	..	1*	<0·0001†	<0·0001*	<0·0001†	<0·0001*	<0·0001†	<0·0001*

Safety and immunogenicity of a live attenuated influenza H5 candidate vaccine strain A/17/turkey/Turkey/05/133 H5N2 and its priming effects for potential pre-pandemic use: a randomised, double-blind, placebo-controlled trial

Punnee Pitisuttithum, Kobporn Boonnak, Supat Chamnanchanunt, Pilaipan Puthavathana, Viravarn Luvira, Hatairat Lerdsamran, Jaranit Kaewkungwal, Saranath Lawpoolsri, Vipa Thanachartwet, Udomsak Silachamroon, Wanibtisam Masamae, Alexandra Schuetz, Ponthip Wirachwong, Sit Thirapakpoomanunt, Larisa Rudenko, Erin Sparrow, Martin Friede, Marie-Paule Kieny

Summary

Background The emergence of highly pathogenic avian influenza H5N1 viruses has raised concerns about their pandemic potential. Vaccination is the most effective way of preventing influenza. In this study, we investigated the safety and immunogenicity of an avian H5N2 live attenuated influenza vaccine (LAIV H5N2) in healthy Thai adults and its priming immune responses with an H5N1 inactivated vaccine boost.

Methods This study was done at the Vaccine Trial Centre at Mahidol University, Bangkok, Thailand and was divided into two parts. Part 1 consisted of a randomised, double-blind, placebo-controlled trial done over 18 months. We randomly assigned (2:1) healthy Thai adults aged 18–49 years with a computer generated randomisation sequence (blocks of six) to receive either two intranasal doses (0·25 mL per nostril) of LAIV H5N2 (101 participants) or placebo (51 participants) 21 days apart. For part 2, an open-label trial was done in which previously vaccinated participants (40 from LAIV H5N2 group and 20 placebo) were given one intramuscular dose (0·5 mL) of H5N1 booster vaccine. Participants, investigators, and site-study workers were blinded from randomisation. Immune responses after subsequent immunisation were evaluated using haemagglutination-inhibition and microneutralisation assays and circulating follicular T-helper cells and plasmablast cells were measured in serum and whole blood. The trials are registered with ClinicalTrials.gov, numbers NCT01841918 and NCT02229357.

Findings Between Feb 4, 2013, and Feb 28, 2013, 256 individuals were screened, of whom 152 participants were enrolled in part 1 of this study. LAIV H5N2 vaccine was well tolerated. Viral shedding was detected in only six (6%) of 101 participants in the vaccine group 1 day after the first vaccination and in and two (2%) of 98 participants in the group after the second vaccination. There was no serious adverse event in both groups. 51 (50%) of 101 participants in the vaccine group and 28 (55%) of 51 in the placebo group reported at least one adverse event. 80 (84%) of 95 events in the vaccine group and 32 (78%) of 43 events in the placebo groups were reportedly suspected adverse events,

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Vaccine Trial Centre (Prof P Pitisuttithum MD, K Boonnak PhD, S Chamnanchanunt MD, V Luvira MD, V Thanachartwet MD), **Center of Excellence for Biomedical and Public Health Informatics** (J Kaewkungwal PhD, S Lawpoolsri MD), **Faculty of Tropical Medicine** (U Silachamroon MD), **Department of Microbiology, Faculty of Medicine, Siriraj Hospital** (Prof P Puthavathana PhD, W Masamae MSc), **and Faculty of Medical Technology**

Inactivated Influenza Vaccine

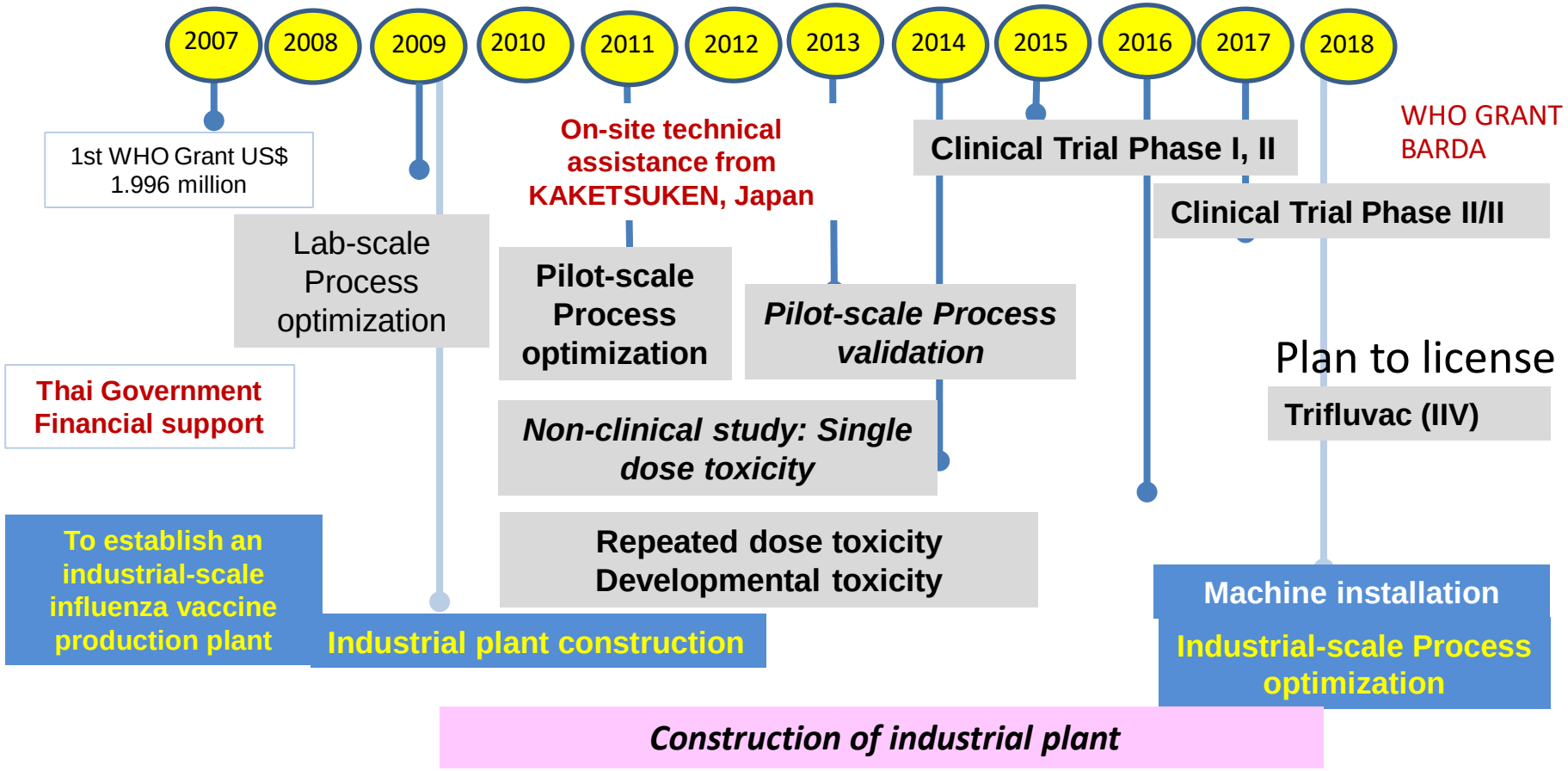
- As a result of a special meeting held by the Ministries of Public Health of the ASEAN countries+3,

the KAKETSUKEN Institute has provided technical assistance :

- The development of technologies to produce seasonal inactivated influenza vaccines on both a pilot and an industrial scale,
- Provide supports in the design of the manufacturing plant,
- The management of the chicken eggs import, the management of documentation and the completing of applications for the registration of the vaccines.

Source: Government Pharmaceutical Organization

Inactivated Vaccine- Trivalent Seasonal IIV



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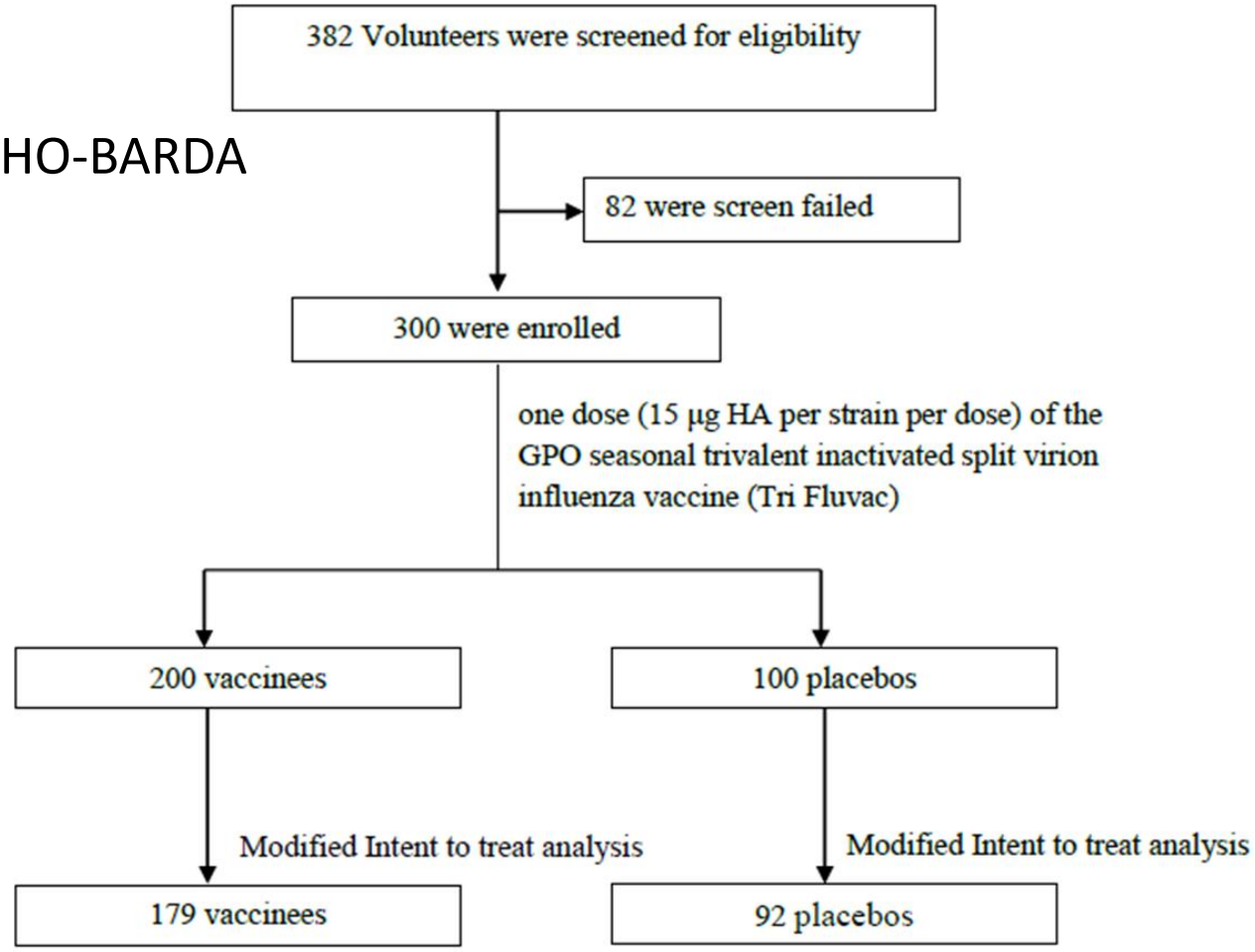
A Phase I/II Randomized Double Blind Controlled Study to Evaluate the Safety and Immunogenicity of GPO Seasonal Trivalent Inactivated Split Virion Influenza Vaccine in Healthy Thai Adults Aged Between 18 yrs to 49 yrs

Supported by WHO-BARDA



Summary of Sero-protection, GMT ratio and Sero- conversion from Baseline (Day 0) (ITT)

Measure	Immunogenicity Criteria	Study Treatment	HAI Assay		
			Flu A H1 antibody titer	Flu A H3 antibody titer	Flu B antibody titer
Day 21					
Sero-protection rate [a]	> 70%	Vaccine (N =200)	100.00 (98.17, 100.00)	98.00 (94.96, 99.45)	84.50 (78.73, 89.22)
		Placebo (N =100)	44.00 (34.08, 54.28)	61.00 (50.73, 70.60)	11.00 (5.62, 18.83)
GMT ratio [b]	> 2.5	Vaccine (N =200)	20.25(16.54 - 24.79)	4.20(3.47 - 5.07)	11.63(9.68 - 13.98)
		Placebo (N =100)	0.99(0.97 - 1.02)	0.97(0.94 - 1.01)	1.02(0.95 - 1.10)
Sero-conversion Rate [c]	> 70%	Vaccine (N =200)	88.00 (82.67, 92.16)	53.50 (46.33, 60.56)	86.50 (80.97, 90.91)
		Placebo (N =100)	0(-)	0(-)	1.00 (0.03, 5.45)
Day 60					
Sero-protection rate [a]	> 70%	Vaccine (N =200)	97.50 (95.64, 99.69)	95.00 (92.19, 98.24)	80.00 (74.62, 86.05)
		Placebo (N =100)	43.00 (33.14, 53.29)	61.00 (50.73, 70.60)	11.00 (5.62, 18.83)
GMT ratio [b]	> 2.5	Vaccine (N =200)	13.06(10.82 - 15.76)	3.19(2.71 - 3.75)	8.40(6.99 - 10.10)
		Placebo (N =100)	0.99(0.97 - 1.02)	0.97(0.92 - 1.02)	1.01(0.95 - 1.09)
Sero-conversion Rate [c]	> 70%	Vaccine (N =200)	83.00 (77.96, 88.68)	46.50 (39.86, 54.17)	76.50 (70.80, 82.91)
		Placebo (N =100)	0(-)	1.00 (0.03, 5.45)	1.00 (0.03, 5.45)
Day 90					
Sero-protection rate [a]	> 70%	Vaccine (N =200)	96.50 (93.55, 98.89)	95.50 (92.23, 98.25)	75.00 (68.79, 81.19)
		Placebo (N =100)	45.00 (35.03, 55.27)	61.00 (50.73, 70.60)	11.00 (5.62, 18.83)
GMT ratio [b]	> 2.5	Vaccine (N =200)	11.45(9.51 - 13.80)	3.03(2.60 - 3.53)	7.33(6.08 - 8.84)
		Placebo (N =100)	1.04(0.96 - 1.11)	1.01(0.96 - 1.08)	1.02(0.95 - 1.10)
Sero-conversion Rate [c]	> 70%	Vaccine (N =200)	81.50 (75.85, 87.00)	46.00 (39.16, 53.42)	73.00 (66.65, 79.37)
		Placebo (N =100)	1.00 (0.03, 5.45)	2.00 (0.24, 7.04)	1.00 (0.03, 5.45)

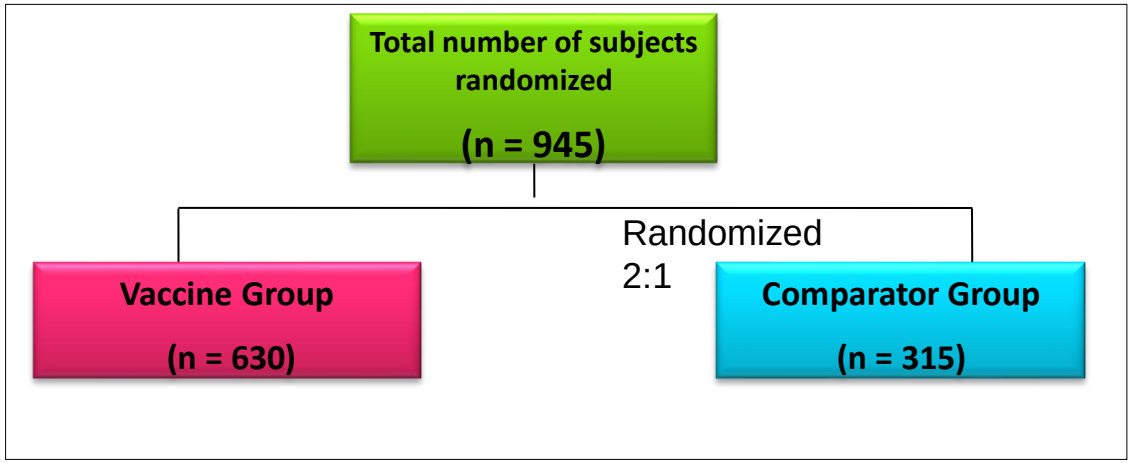
Summary of Sero-protection, GMT ratio and Sero- conversion from Baseline (Day 0) PPP

Measure	Immunogenicity Criteria	Study Treatment	HAI Assay		
			Flu A H1 antibody titer	Flu A H3 antibody titer	Flu B antibody titer
Day 21					
Sero-protection rate [a]	> 70%	Vaccine (N =179)	100.00 (97.96, 100.00)	97.77 (94.38, 99.39)	83.24 (76.95, 88.40)
		Placebo (N = 92)	43.48 (33.17, 54.22)	57.61 (46.86, 67.85)	8.70 (3.83, 16.42)
GMT ratio [b]	> 2.5	Vaccine (N =179)	23.03(18.76 - 28.26)	4.85(4.00 - 5.90)	11.92(9.84 - 14.44)
		Placebo (N = 92)	0.99(0.96 - 1.01)	0.97(0.94 - 1.01)	1.01(0.93 - 1.09)
Sero-conversion Rate [c]	> 70%	Vaccine (N =179)	89.94 (84.57, 93.93)	59.22 (51.64, 66.49)	87.71 (81.99, 92.13)
		Placebo (N = 92)	0(-)	0(-)	1.09 (0.03, 5.91)
Day 60					
Sero-protection rate [a]	> 70%	Vaccine (N =179)	98.32 (96.89, 99.99)	94.41 (91.29, 98.03)	78.21 (72.36, 84.83)
		Placebo (N = 92)	42.39 (32.15, 53.14)	57.61 (46.86, 67.85)	8.70 (3.83, 16.42)
GMT ratio [b]	> 2.5	Vaccine (N =179)	14.62(12.08 - 17.70)	3.58(3.03 - 4.24)	8.45(6.98 - 10.23)
		Placebo (N = 92)	0.99(0.96 - 1.01)	0.97(0.92 - 1.02)	1.00(0.93 - 1.08)
Sero-conversion Rate [c]	> 70%	Vaccine (N =179)	85.47 (80.50, 91.12)	51.40 (44.36, 59.53)	77.09 (71.13, 83.84)
		Placebo (N = 92)	0(-)	1.09 (0.03, 5.91)	1.09 (0.03, 5.91)
Day 90					
Sero-protection rate [a]	> 70%	Vaccine (N =179)	97.21 (94.35, 99.38)	94.97 (91.34, 98.04)	73.18 (66.48, 79.91)
		Placebo (N = 92)	44.57 (34.19, 55.30)	57.61 (46.86, 67.85)	8.70 (3.83, 16.42)
GMT ratio [b]	> 2.5	Vaccine (N =179)	12.72(10.50 - 15.40)	3.37(2.87 - 3.96)	7.31(6.01 - 8.90)
		Placebo (N = 92)	1.03(0.95 - 1.11)	1.02(0.96 - 1.08)	1.02(0.94 - 1.10)
Sero-conversi on Rate [c]	> 70%	Vaccine (N =179)	84.36 (78.70, 89.76)	50.84 (43.53, 58.67)	73.18 (66.48, 79.91)
		Placebo (N = 92)	1.09 (0.03, 5.91)	2.17 (0.26, 7.63)	1.09 (0.03, 5.91)

GPO Tri Fluvac Vaccine Phase II/III

STUDY DESIGN

- Phase II/III, non-inferiority double-blinded, randomized, and controlled trial
- Study Site: Vaccine Trial Centre or its mobile sites, Faculty of Tropical Medicine, Mahidol University.



Clinical part has been completed up to D90 FU
July 2017- Feb 2018

Supported by WHO-BARDA

Inactivated Influenza Vaccine

- Industrial plant is situated in Tub Kwang Sub-District, Kaeng Khoi District, Saraburi Province and is being built with a budget of 1,116.19 million Baht.
- The goal of the plant is to have the capacity to produce 2 million doses of seasonal influenza vaccines. THEN increase to 10 million doses in the

- Able to increase up to 60 M DOSE DURING EPIDEMIC/OUTBREAK

Source: Government Pharmaceutical Organization

2014: A Starting Year for Regional Collaborative Initiatives on ASEAN Vaccine Security and Self-Reliance (AVSSR)

- In the late 2013, National Vaccine Committee (NVC) took note of the official establishment of ASEAN Community in 2015 and the urgent need to develop an ASEAN-specific, post-2015 health development agenda

ASEAN Price Policy for Vaccine (APPV) and Pooled Procurement

Source: National Vaccine Institute

Roadmap for Thailand to be world class key player vaccine and biological producer

1 Strengthen Vaccine Security

Vaccine and biological products
- **Manufacture 3 EPI vaccines:- DTP, dT, Flu**

Infrastructure Development
- Bioresource Center, Pilot plant, Animal Testing Center

2 Vaccine Self-Reliance

Vaccine and biological products
- Manufacture 3 EPI vaccines:- DTP-HB, MR, MMR
- Manufacture new drugs/biological products for cancer and infectious diseases.

3 ASEAN Key Player Vaccine Producer

Vaccine and biological products
- Manufacture a combined vaccine:- DTP-HB, HIB, IPV
- Manufacture a new EPI vaccine:- IPV/HPV
- Manufacture new drugs/biological products for cancer and infectious diseases.
- Increase manufacturing capacity of animal vaccines

4 Expand to animal Vaccine and Biological Products

Vaccine and biological products
- Manufacture a new vaccine for adult (Varicella/Pneumococcal)
- Manufacture new drugs/biological products for cancer, infectious diseases, and NCDs.
- Manufacture 5 new animal vaccines

World class key player vaccine and biological products

Stage 1	2560-2564	Stage 2	2565-2569	Stage 3	2570-2574	Stage 4	2575-2579

Source: National Vaccine Institute

Executive Summary

Report of the assessment of

the sustainability of pandemic influenza preparedness (PIP) in Thailand

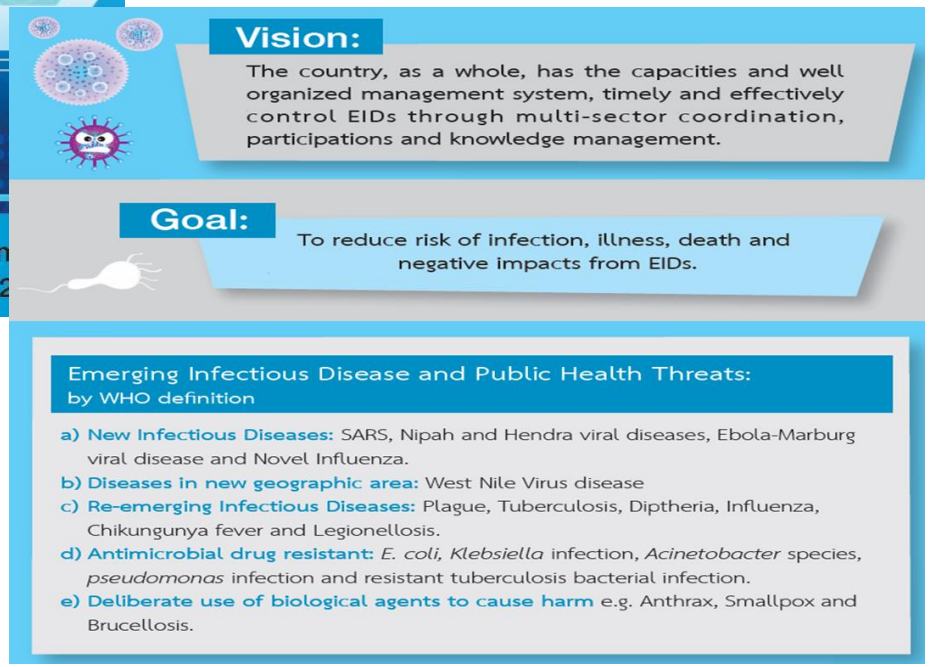
Dr. Supamitr-PI

- Strategic areas under assessment include (1) pandemic influenza preparedness planning, (2) surveillance, (3) influenza immunization, (4) risk communication, (5) influenza vaccine development and production, and (6) the regulatory of influenza vaccine; with emphases on the latter two areas.

Key recommendations

Ensure access to pandemic influenza vaccine

- The strategy and plan should include essential functions such as transportation, training and public communication and monitoring.
- The plan could be prepared as part of public health emergency response plan, and should be periodically tested in simulation exercises to ensure its feasibilities. (Main targets of recommendation: DDC, GPO, NVI)



LAIV or IIV in the event of pandemics????

Source: Bureau of Emerging Infectious Diseases, Department of Disease Control, Ministry of Public Health

CONCLUSION

Successful program in helping local manufacturer (GPO)

To be able to manufactured its own influenza vaccine as part of self reliance as part of national security

Challenges remain for continuous policy support and sustainability

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