OFFLU avian influenza virus characterisation meeting
29 – 30 March 2017
FAO Headquarters, Rome, Italy

WHO vaccine composition meeting (VCM) process

OFFLU-WHO agreement signed in 2011 further extended from 2014 – 2018

OFFLU and WHO extend their collaboration for pandemic preparedness

Paris, 21 October 2013 - The World Organisation for Animal Health (OIE) and the Food and Agriculture Organization of the United Nations (FAO) have signed with the World Health Organization (WHO) an agreement allowing the extension of their cooperation on the contribution of animal health data to the WHO human Influenza Vaccine Virus Selection Process for an additional period of five years.

OIE and FAO are jointly managing OFFLU, a global network of high level expertise on animal influenza. One of the core objectives of this network is to share animal influenza data with WHO in order to assist with selection of the most appropriate viruses for human vaccines, which can include animal viruses that present a potential to emerge into pandemic threats. The first such agreement was signed by the three sister organisations in January 2011. Since then, OFFLU has collected data about avian influenza viruses isolated from animal samples by the OIE and the FAO Reference Centres, to identify which strains of virus should be relevant for use in human vaccines. These data continue to provide a cornerstone for human pre-pandemic preparedness and for WHO's ability to understand the potential public health risks arising from influenza viruses circulating in animal populations.

Given the success of this mechanism, the OIE, FAO and WHO agreed on the extension of the agreement from 1 January 2014 to 31 December 2018 and remain committed, as stated in their Tripartite Agreement, to further close collaboration on biological risks at the human-animal interface.

Vaccine Composition Meeting (VCM) /1

Why? The periodic replacement of viruses contained in *human* influenza vaccines is necessary in order for the vaccines to be effective due to the constant evolving nature of influenza viruses, including those circulating and infecting humans.

When? twice annually

Who? representatives from:

- WHO Collaborating Centres for influenza (CCs) of GISRS;
- WHO Essential Regulatory Laboratories (ERLs) of GISRS;
- National Influenza Centres and WHO H5 Reference Laboratories of GISRS;
- WHO Collaborating Centre for Modelling, Evolution, and Control of Emerging Infectious Diseases; and
- OIE/FAO Network of expertise on animal influenza (OFFLU).

Vaccine Composition Meeting (VCM) /2

- **MAIN GOAL**: to ensure that existing ***human*** **candidate vaccine viruses** (CVV) will protect against circulating strains. An online report summarizing the analysis and selection (if any) of new *human* CVVs and/or potency testing reagents is posted after each meeting.
- **HOW?** Review global virus activity, genetic, and antigenic analyses for viruses circulating in previous 6-month period:
  - human seasonal viruses, and
  - viruses with zoonotic and pandemic potential
    - Selection of reference viruses and zoonotic CVVs where needed for ***human*** **vaccines to ensure pandemic preparedness** (NOTE: selection does not imply a recommendation for initiating manufacture)

OFFLU VCM Contribution

- OFFLU contributes specifically to the VCM Zoonotic online report; this report *does not* contain sensitive or confidential data that may have been shared for analysis
- Changes in the genetic and antigenic characteristics of these viruses relative to existing *human* CVVs, and their potential risks to public health, may justify the need to select and develop new *human* CVVs.
- *Human* CVVs are selected and developed **for potential use** in *human* vaccines to ensure pandemic preparedness and aid in ability to produce the *human* vaccine if needed.

OFFLU VCM Contribution

Influenza A(H5) candidate vaccine viruses

The available and pending A(H5) CVVs are listed in Table 2. As the viruses continue to evolve new A(H5) CVVs may be developed.

Table 2. Status of influenza A(H5) candidate vaccine virus development

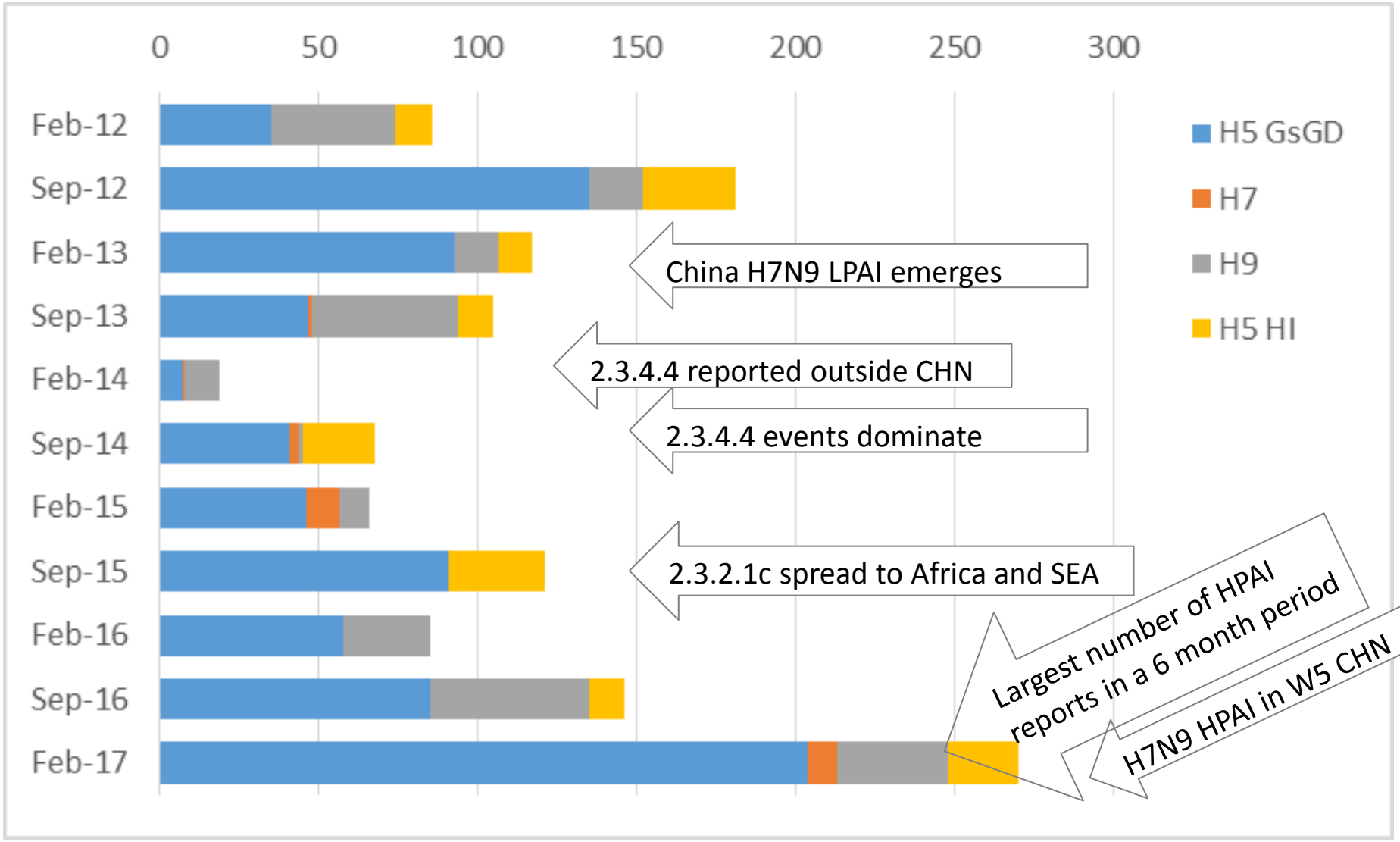
Candidate vaccine viruses	Clade	Institution*	Available
A/Viet Nam/1203/2004 (CDC-RG; SJRG-161052)	1	CDC and SJCRH	Yes
A/Viet Nam/1194/2004 (NIBRG-14)	1	NIBSC	Yes
A/Cambodia/R0405050/2007 (NIBRG-88)	1.1	NIBSC	Yes
A/Cambodia/X0810301/2013 (IDCDC-RG34B)	1.1.2	CDC	Yes
A/duck/Hunan/795/2002 (SJRG-166614)	2.1.1	SJCRH/HKU	Yes
A/Indonesia/5/2005 (CDC-RG2)	2.1.3.2	CDC	Yes
A/Indonesia/NIHRD11771/2011 (NIIDRG-9)	2.1.3.2a	NIID	Yes
A/bar-headed goose/Qinghai/1A/2005 (SJRG-163222)	2.2	SJCRH/HKU	Yes
A/chicken/India/NIV33487/2006 (IBCDC-RG7)	2.2	CDC/NIV	Yes
A/whooper swan/Mongolia/244/2005 (SJRG-163243)	2.2	SJCRH	Yes
A/Egypt/2321-NAMRU3/2007 (IDCDC-RG11)	2.2.1	CDC	Yes
A/turkey/Turkey/1/2005 (NIBRG-23)	2.2.1	NIBSC	Yes
A/Egypt/N03072/2010 (IDCDC-RG29)	2.2.1	CDC	Yes
A/Egypt/3300-NAMRU3/2008 (IDCDC-RG13)	2.2.1.1	CDC	Yes
A/Egypt/N04915/2014 (NIBRG-306)	2.2.1.2	NIBSC	Yes
A/common magpie/Hong Kong/5052/2007 (SJRG-166615)	2.3.2.1	SJCRH/HKU	Yes
A/Hubei/1/2010 (IDCDC-RG30)	2.3.2.1a	CDC	Yes
A/duck/Bangladesh/19097/2013 (SJ007)	2.3.2.1a	SJCRH	Yes
A/barn swallow/Hong Kong/D10-1161/2010 (SJ003)	2.3.2.1b	SJCRH/HKU	Yes
A/duck/Viet Nam/NCVD-1584/2012 (NIBRG-301)	2.3.2.1c	NIBSC	Yes
A/chicken/Hong Kong/AP156/2008 (SJ002)	2.3.4	SJCRH/HKU	Yes
A/Anhui/1/2005 (IBCDC-RG6)	2.3.4	CDC	Yes
A/duck/Laos/3295/2006 (CBER-RG1)	2.3.4	FDA	Yes
A/Japanese white eye/Hong Kong/1038/2006 (SJRG-164281)	2.3.4	SJCRH/HKU	Yes
A/chicken/Bangladesh/11rs1984-30/2011 (IDCDC-RG36)	2.3.4.2	CDC	Yes
A/Guizhou/1/2013 (IDCDC-RG35)	2.3.4.2	CDC/CCDC	Yes
A/Sichuan/26221/2014 (IDCDC-RG42A) (H5N6)	2.3.4.4	CDC/CCDC	Yes
A/gyrfalcon/Washington/41088-6/2014 (IDCDC-RG43A) (H5N8)	2.3.4.4	CDC	Yes
A/goose/Guiyang/337/2006 (SJRG-165396)	4	SJCRH/HKU	Yes
A/chicken/Viet Nam/NCVD-016/2008 (IDCDC-RG12)	7.1	CDC	Yes
A/chicken/Viet Nam/NCDV-03/2008 (IDCDC-RG25A)	7.1	CDC	Yes
A/environment/Hubei/950/2013	7.2	CDC/CCDC	Yes
Candidate vaccine viruses in preparation	**Clade**	**Institution**	**Availability**
A/chicken/Guiyang/1153/2016-like	2.3.2.1c	SJCRH/HKU	Pending
A/chicken/Ghana/20/2015-like	2.3.2.1c	CDC	Pending
A/chicken/Viet Nam/NCVD-15A59/2015-like (H5N6)	2.3.4.4	SJCRH	Pending
A/Hubei/29578/2016-like (H5N6)	2.3.4.4	CCDC	Pending
A/duck/Hyogo/1/2016-like (H5N6)	2.3.4.4	NIID	Pending

*** Institutions developing and/or distributing the candidate vaccine viruses:**
CDC - Centers for Disease Control and Prevention, United States of America
NIV - National Institute of Virology, India
CCDC - Chinese Center for Disease Control and Prevention
FDA - Food and Drug Administration, United States of America
HKU – University of Hong Kong, Hong Kong Special Administrative Region, China.
NIBSC - National Institute for Biological Standards and Control, a centre of the Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom
NIID - National Institute of Infectious Diseases, Japan
SJCRH - St Jude Children's Research Hospital, United States of America

Latest list of CVVs selected for potential human pandemic preparedness vaccines available open-access report via WHO website

http://www.who.int/influenza/vaccines/virus/characteristics_virus_vaccines/en

OFFLU Data Contributions 2012-2017



What does OFFLU offer the VCM?

- Summarize the **global animal virus activity** in animal populations (e.g. goose/Guangdong H5, H7N9, H9N2).
- Report on the **genetic** and **antigenic** characteristics of recent zoonotic related viruses circulating in animals relevant to *human* CVV updates.
- Contribute to **pandemic preparedness** through the selection and development of new *human* CVVs, if needed
- **Share viruses that have zoonotic or pandemic potential** from animals to ensure evaluation by the public health sector (eg. clade 2.3.4.4 H5Nx).
- Help to identify animal influenza viruses with zoonotic potential, **before spillover occurs**.

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What can you do? /1

- In order to provide an overview of global animal virus activity, and report on the genetic and antigenic characteristics of recent zoonotic influenza viruses and related viruses circulating in animals relevant to *human* CVV updates, OFFLU:
- Coordinates the previous 6 months data for avian influenza viruses with pandemic potential (**H5, H7, H9**) from OIE/FAO AI Reference Labs, Regional and National Vet Labs
  - Both **non-public** and **public HA** gene sequences are valuable
  - With **epidemiological**, **outbreak** and **sample metadata** where available
  - Where analysis has been conducted, sharing of standardised clade/lineage ID is extremely helpful

What can you do? /2

- In order to make inferences on antigenic matching to existing *human* CVVs, the antigenic analysis is conducted using a WHO-CC GISRS (SJCRH & CDC) reference panel with ferret antisera – these reagents are limited in quantity and expensive to generate.
- While HI testing is a routine process for animal health laboratories…HI testing using a ferret reference panel is not.
- Designated OFFLU Reference Labs (AAHL, APHA, IZSVe) have this capacity, and because this testing requires virus, **sharing of virus isolates to these labs** allows this data to be generated.

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What does OFFLU offer Contributors? /1

- **Timely confirmation** and assistance with **advanced characterisation** of outbreak viruses

- Assistance in **collating** molecular virus and epidemiological **data for official notification** of disease outbreaks as authorised by the origin country (e.g. to national authorities, the OIE, GenBank, high-impact publications, etc)

- OFFLU Ref Labs (AAHL, APHA, IZSVe) produce **antigenic data** using WHO standardised antigenic panels for pandemic preparedness where viruses are shared

What does OFFLU offer Contributors? /2

- Timely **identification** of **emerging** or **novel reassortant** viruses and rapid development of **new regional diagnostic tests** (eg. 2.3.4.4 H5N6 real-time PCR in SEA)

- **Recognition** and **acknowledgement** of the country's contribution by the international tripartite organizations (WHO/OIE/FAO) & members of the OFFLU Regional Network.

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Egypt
India (Bhopal)
Iran
Iraq
Israel
Italy (IZSVe)
Japan
Lao PDR
Libya
Myanmar
Nepal
Niger
Nigeria
Palestinian Authority
Romania
Russia
Turkey
Vietnam
UK (APHA)
US (NVSL)