

<b>GVIRF 2018 Workshop 5: Epidemic and Pandemic Preparedness</b>	
<b>Rapporteur:</b> Erin Sparrow (WHO), Angela Hwang (Consultant)	
<b>Session Outline</b>	<p><b>Chair:</b> Martin Friede (Coordinator, Initiative for Vaccines Research, WHO)</p> <p><b>Presentations:</b></p> <p><i>WHO R&amp;D Blueprint Update: progress and plans</i>, Martin Friede, (Coordinator, Initiative for Vaccines Research, WHO)</p> <p><i>Influenza pandemic risk and preparedness</i>, John Tam (Visiting Professor, The Hong Kong Polytechnic University; Director and Chairman Asia-Pacific Alliance for the Control of Influenza)</p> <p><i>Epidemic Preparedness: National Security for Thailand</i>, Punnee Pitisuttithum (Faculty of Tropical Medicine, Mahidol University)</p> <p><i>Universal influenza vaccines and their role in preparedness</i>, Jennifer Gordon (Scientific Program Manager, Respiratory Diseases Branch, Division of Microbiology &amp; Infectious Diseases, NIAID)</p>
<b>Objectives of the session</b>	<p><i>To discuss:</i></p> <ul style="list-style-type: none"> <li>the development of vaccines that can be deployed during epidemic and pandemic threats against which current tools are insufficient</li> <li>global coordination to address epidemic and pandemic threats</li> </ul>
<b>Main outcome</b>	<ul style="list-style-type: none"> <li>Vaccines for epidemic and pandemic preparedness do not have viable markets and therefore need to be supported as a public good.</li> <li>A universal influenza vaccine could address the failure of the pandemic influenza vaccine market by serving as both a seasonal and a pandemic influenza vaccine: ongoing demand for seasonal use would maintain capacity at the ready in the event of a pandemic.</li> </ul>
<b>Summary</b>	<p>The WHO R&amp;D <i>Blueprint for Action to Prevent Epidemics</i> aims to shorten the time between the declaration of a public health emergency of international concern and the availability of effective diagnostics, therapeutics and vaccines.<sup>a</sup> It was created out of the 2014 Ebola crisis, which saw significant delays to the field testing of candidate vaccines and drugs. This led to calls for improving coordination, fostering an enabling environment for research and development for diseases of epidemic potential, and developing norms and standards tailored to the epidemic context. Crimean-Congo haemorrhagic fever, Ebola virus disease, Marburg virus disease, Lassa fever, Middle East respiratory syndrome coronavirus, Severe Acute Respiratory Syndrome, Nipah and henipaviral diseases, Rift Valley fever and Zika have been identified as priority diseases. R&amp;D roadmaps, target product profiles, and approaches to regulatory pathways and ethical issues, clinical trial design, and data and sample sharing are being formulated for these diseases. The Global Coordination Mechanism is playing a central role in coordinating interactions amongst key R&amp;D partners to better enable and support preparedness and research.</p> <p>Pandemic influenza is also a significant threat since there will be a long delay to supply of adequate quantities of pandemic strain-specific vaccine. Coordinated</p>

	<p>global efforts are underway to improve influenza pandemic preparedness. To provide guidance to countries, the WHO <i>Pandemic Influenza Risk Management</i> guidelines have been issued and revised multiple times since 2009.<sup>b</sup> It recommends a risk-based and integrated approach to pandemic influenza preparedness. However, more than half of countries do not have publicly available plans, and many existing plans are outdated or incomplete.</p> <p>Vaccines are essential to limit the spread and severity of influenza pandemics. Because manufacturing capacity is unable to match the timing and volume required for pandemic control, thirteen developing countries have been partnering with WHO to build domestic influenza vaccine manufacturing capacity. Notably, Thailand is now developing and manufacturing influenza vaccines. It has developed and obtained emergency use authorizations for live-attenuated H1N1 and avian H5N2 vaccines and showed that the live-attenuated H5N2 vaccine can be used in combination with an inactivated H5N1 vaccine in a heterologous prime-boost strategy.<sup>c</sup> A Phase 2/3 non-inferiority study of a trivalent inactivated seasonal influenza vaccine is nearing completion. A full-scale inactivated vaccine manufacturing facility is being constructed and will have a capacity of 2-10 million doses of seasonal vaccine or 60 million doses of adjuvanted monovalent vaccine during a pandemic.</p> <p>Universal influenza vaccines would transform both seasonal and pandemic influenza prevention. Due to cross-protection, annual vaccine reformulation would no longer be necessary and doses could be stockpiled for rapid deployment in the event of a pandemic. To facilitate development of a universal influenza vaccine, NIAID has established a definition for universal influenza vaccines, described a research agenda for vaccine development, and is funding, conducting, and providing technical assistance for influenza vaccine research.<sup>d</sup></p>
<p><b>Key references</b></p>	<p>a. An R&amp;D Blueprint for Action to Prevent Epidemics: Plan of Action, WHO May 2016.  <a href="http://www.who.int/blueprint/about/r_d_blueprint_plan_of_action.pdf?ua=1">www.who.int/blueprint/about/r_d_blueprint_plan_of_action.pdf?ua=1</a></p> <p>b. Pandemic Influenza Risk Management: A WHO guide to inform &amp; harmonize national &amp; international pandemic preparedness and response, WHO May 2017. <a href="http://www.who.int/influenza/preparedness/pandemic/influenza_risk_management_update2017/en/">http://www.who.int/influenza/preparedness/pandemic/influenza_risk_management_update2017/en/</a></p> <p>c. Pitisuttithum P, Boonnak K, Chamnanchanunt S, Puthavathana P, Luvira V, Lerdsamran H, et al. 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. <i>Lancet Infect Dis</i> 2017;17:833–42. doi:10.1016/S1473-3099(17)30240-2.</p> <p>d. Paules CI, Marston HD, Eisinger RW, Baltimore D, Fauci AS. The Pathway to a Universal Influenza Vaccine. <i>Immunity</i> 2017;47:599–603. doi:10.1016/j.immuni.2017.09.007.</p>