

Meeting of Strategic Advisory Group of Experts (SAGE) on Immunization, 18–20 October 2016

DECLARATION OF INTERESTS

All 15 SAGE members participating in the meeting updated their declaration of interest ahead of the meeting. Seven SAGE members reported relevant interests, which were assessed not to constitute a conflict of interest and it was assessed that all members could fully participate in all sessions. All the reported relevant interests are summarized below:

Ilesh Jani:

- Serves as a site principal investigator for a clinical trial evaluating the safety, tolerability and immunogenicity of two prime-boost regimens of the candidate prophylactic vaccines for Ebola Ad26.ZEBOV and MVA-BN-Filo funded by Janssen Vaccines & Prevention B.V., and the Joint Vaccine Acquisition Program (JVAP). This interest was assessed as non-personal, non-specific and financially significant*.
- Serves as principal investigator for phase 2b study to evaluate the safety and efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection in women in sub-Saharan Africa funded by the US National Institutes of Health (NIH), the HIV Vaccine Trial Network (HVTN) and the U.S. Military HIV Research Program (MHRP). This interest was assessed as non-personal, non-specific and financially significant*.

Terence Nolan:

- His institution¹ receives research support from 2016-2019 from Novavax to participate in a large multicenter RCT of an RSV-F experimental vaccine administered to pregnant women. Participated in an investigator initiation and training meeting for the trial. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ receives research support in 2015-19 to conduct a candidate 2-component Meningococcal B vaccine Phase 2 study in toddlers from Pfizer. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ received research support in 2015 from GSK/Novartis to conduct a study of Meningococcal B vaccine. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ receives research support in 2015-2017 to conduct a study in pregnant women and their offspring on dTap vaccine. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ received research support until 2014 to conduct an influenza cell-based vaccine clinical trial from Novartis. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ received research support in 2015-2016 to conduct a follow-up clinical trial on a birth dose of Pertussis Vaccination from GSK. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ receives research support from 2013-2016 to conduct a Meningococcal ACWY vaccine clinical trial from GSK. This interest was assessed as non-personal, non-specific and financially significant*.
- Serves as principal investigator for a clinical trial assessing the antibody response and persistence following MenACWY-TT funded by GSK and Murdoch Children's Research Institute. This interest was assessed as non-personal, non-specific and financially significant*.
- Served on a GSK Pertussis Scientific Advisory Board, Buenos Aires in April 2016 on pertussis vaccination and new vaccine development for use in pregnancy and for the elderly. This interest was assessed as non-personal, non-specific and financially significant*.
- Served on a GSK Pertussis Scientific Advisory Board, London in March 2014. This interest was assessed as non-personal, non-specific and financially significant*.
- Received a payment for contributing to pertussis education program development and speakers' bureau by Medscape funded by an untied educational grant from GSK in 2015 and 2016. This interest was assessed as personal, non-specific and financially significant*.

¹ As per WHO assessment of conflicts of interests, "Institution" relates only to the expert's research/or work unit, as subdivision of the department

Kate O'Brien:

- Serves as technical expert consultant for Merck, ClearPath, Affinivax and PATH on pneumococcal vaccination. This interest was assessed as non-personal, non-specific and financially insignificant*.
- Served as member of DSMB on malaria RTS,S vaccine funded by PATH-Malaria Vaccine Initiative. This ceased in 2014. This interest was assessed as non-personal, non-specific and financially significant*.
- Received funding for travel costs for a GSK Grand Convergence Meeting in 2015. This interest was assessed as non-personal, non-specific and financially insignificant*.
- Her institution¹ currently receives research grants from GSK, Gavi, BMGF regarding pneumococcal, rotavirus vaccines, technical country support and decision making on pneumococcal/rotavirus vaccine, vaccine demand support, and/or pneumonia etiology. This interest was assessed as non-personal, non-specific and financially significant*. Her institution¹ received research grants from the National Institutes of Health (NIH) regarding PCV 13. This interest was assessed as non-personal, non-specific and financially significant*.
- Her institution¹ currently receives research grants from Merck on the value of adult vaccine preventable diseases. Her institution¹ received research grants from Merck on the adult vaccine initiative until June 2016. This interest was assessed as non-personal, non-specific and financially significant*.

Andrew Pollard:

- His institution¹ received research support until 2014 from GSK on Pneumococcal vaccine. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ received research support expected to end in 2016 from Okairos on RSV vaccine. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ received research support until 2015 from Pfizer on Meningococcal B vaccine, meningitis epidemiology and pneumococcal epidemiology. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ received research support until 2014 from Novartis on Meningococcal B vaccine. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ received research support on a grant for a study on an Ebola vaccine developed by Janssen (2015-current) funded by a European Commission IMI grant (EBOVAC). This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ received research support on a grant for a study on the cause of fever with Bexsero funded by a European Commission grant (EUCLIDS; funding 2011-2016). The vaccine for the study is provided by Novartis/GSK. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ received research support on a grant for a study on the efficacy of a typhoid vaccine (Tybar-CV) produced by Bharat Biotech, India (2013-2016) funded by the Bill and Melinda Gates Foundation. No funding was received from Bharat Biotech, the grant was funded by the Bill and Melinda Gates Foundation. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ received research support on a grant for a study on the genes expressed in children when they receive an adjuvanted influenza vaccine (FluAd, Novartis) funded by a European Commission grant (ADITEC, 2011-2016). This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ received research support on a grant for a study on the treatment of encephalitis in children with intravenous immunoglobulin (supply and distribution funding agreement with CSL Behring) funded by the National Institute for Health Research (2015-2020). This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ received research support on a grant for a study on the infant pneumococcal vaccine schedule in Nepal (2013-2017), funded by Gavi, the Vaccine Alliance. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ received unrestricted educational grants from Novartis/GSK/Astra Zeneca/Sanofi Pasteur MSD in 2014; Novartis/GSK/Astra Zeneca in 2015 and Pfizer/GSK/Astra Zeneca in 2016 for a course on infection and immunity in children. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution¹ received research support until 2014 from SPMSD on a hexavalent infant vaccine. This interest was assessed as non-personal, non-specific and financially significant*.

Claire-Anne Siegrist:

- Developed and owns the Viavac immunization management software destined to support Swiss health care professionals to follow the official immunization recommendations. This interest was assessed as personal, non-specific and financially significant*.
- Owns a patent for the neonatal use of a DC-chol adjuvant. This interest was assessed as personal, non-specific and financially insignificant*.
- Owns a patent for the use of Viaskin as an epicutaneous booster. This interest was assessed as personal, non-specific and financially insignificant*.
- Her institution¹ receives a research grant from Sanofi Pasteur on the immunology of novel adjuvants in preclinical pertussis immunization models. This interest was perceived as non-personal, non-specific and financially significant*.
- Her institution¹ received a research grant in 2015 for a phase I clinical trial of the VSV-ZEBOV Ebola vaccine supported by the Wellcome Trust. This interest was perceived as non-personal, non-specific and financially significant*.
- Her institution¹ receives a research grant from DBV technologies for a Phase I proof-of-concept study of an epicutaneous pertussis booster with Viaskin. This interest was perceived as non-personal, non-specific and financially significant*.
- Receives consultancy fees and travel costs from DBV technologies. This interest was perceived as personal, non-specific and financially insignificant*.
- Chairs the "Fondation mesvaccins.ch" which receives an unrestricted grant from GSK, Sanofi Pasteur MSD and Pfizer to promote the use of the Swiss electronic immunization record. This interest was perceived as non-personal, non-specific and financially significant*.
- Receives consultancy fees and travel costs from BioNet Asia. This interest was perceived as personal, non-specific and financially insignificant*.
- Her institution¹ received a research grant in 2015 for a deep immunomonitoring of vaccine responses to the VSV-ZEBOV Ebola vaccine supported by the Innovative Medicine Initiative (IMI). The interest was perceived as non-personal, non-specific and financially significant*.

Nikki Turner:

- Her institution¹ received a research grant from GSK for a vaccine effectiveness trial of conjugate pneumococcal PCV10 vaccine. This interest was perceived as non-personal, non-specific and financially significant*.
- Her institution¹ receives a research grant from GSK to assess the safety of pertussis vaccine during pregnancy. This interest was perceived as non-personal, non-specific and financially significant*.
- The Immunisation Advisory Centre, for which she serves as the Director, ran a one-day symposium - the NZ Influenza Symposium on the 12 November 2014, and they accepted sponsorship from Sanofi, GSK, Abbott and MSD. None of the speakers were funded and the sponsorship had no involvement in the setting of the programme. This interest was assessed as non-personal, non-specific and financially significant*.
- The Immunisation Advisory Centre, for which Nikki Turner is the Director, ran a national immunisation conference in September 2015 with sponsorship from GSK, Myland EPD, Sanofi, Pfizer, Pharmacia, bioCSL, MSD, Bell Technology, Rollex Medical, Green Cross Health, Obtain and Temprecord. None of the speakers were funded and the sponsorship had no involvement in the setting of the programme. This interest was assessed as non-personal, non-specific and financially significant*.

Fred Were:

- Serves on the safety monitoring committee for an evaluation of i.v. injection of vialled *P. falciparum* sporozoites until 2018. The sporozoite product is developed by Sanaria. This interest was assessed as non-personal, non-specific and financially insignificant*.
- Serves on the PATH advisory board for the whole cell pneumococcal vaccine from 2018. This interest was assessed as non-personal, non-specific and financially insignificant*.

* According to WHO's Guidelines for Declaration of Interests (WHO expert), an interest is considered "personal" if it generates financial or non-financial gain to the expert, such as consulting income or a patent. "Specificity" states whether the declared interest is a subject matter of the meeting or work to be undertaken. An interest has "financial significance" if the honoraria, consultancy fee or other received funding, including those received by expert's organization, from any single vaccine manufacturer or other vaccine-related company exceeds 5,000 USD in a calendar year. Likewise, a shareholding in any one vaccine manufacturer or other vaccine-related company in

excess of 1,000 USD would also constitute a “significant shareholding”. Funding going to the SAGE member’s research unit needs to be declared.

The above summary of reported interests was made available for public notice and comment on the WHO SAGE website prior to the October 2016 SAGE meeting. No comments have been received.