# Meeting of Strategic Advisory Group of Experts (SAGE) on Immunization, 17–19 April 2018

#### **DECLARATION OF INTERESTS**

All 14 SAGE members participating in the meeting updated their declaration of interest ahead of the meeting. Eight SAGE members reported relevant interests, which were assessed not to constitute a conflict of interest in relation to the agenda of the meeting, 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 a site 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 and for a for phase 1/2a study to evaluate the safety and immunogenicity of clade C ALVAC-HIV (vCP2438) and Bivalent Subtype C gp120 alone, with MF59® adjuvant, and with alum adjuvant in healthy, HIV-uninfected adult participants, both 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\*.

#### Noni MacDonald:

- Served as consultant in regard to vaccine-related issues (Facilitator Annual Retreat Supporting National Independent Immunization and Vaccine Advisory Committees (SIVAC) Report January, 2016; Facilitator Global Staff Retreat of the WHO Vaccine Preventable Diseases Programme Area Network March, 2016; Facilitator Meeting of the International Network of NITAGs May, 2016; Consultant WHO EURO Sub-regional technical consultation on vaccination opposition. June, 2016; Facilitator Vaccination in humanitarian emergency situations. October 2016; Consultant Ontario Ministry of Health and Longterm Care. January, 2017; Facilitator 2nd Global NITAG Network meeting Berlin June 2017; development of a guidance document on vaccine hesitancy in July 2017) to WHO and WHO collaborating center; chaired/facilitated NITAG partners meeting Jan 2018. Each interest was assessed as personal, non-specific and financially insignificant\*.
- Her institution<sup>1</sup> received a grant/research support from WHO until 2016 to conduct a
  systematic review of global surveillance for adverse events following immunization
  during pregnancy. This interest was assessed as non-personal, non-specific and
  financially insignificant\*.
- Her institution<sup>1</sup> received research support from WHO until 2017 to survey obstetricians/ gynecologists& midwives on their perception of product monographs and influenza vaccines safety in pregnancy. This interest was assessed as non-personal, non-specific and financially significant\*.

<sup>&</sup>lt;sup>1</sup> Dalhousie University, IWK Health Centre, Canada

- Her institution¹ receives grants from the Canadian Institutes of Health Research to conduct studies on a) vaccine pain and hesitancy for which she serves as on co-investigator; b) vaccine uptake and contributing factors in youth with autism spectrum disorder at several sites across Canada for which she serves as co-investigator; c) health outcomes in children of mothers who received influenza vaccination during pregnancy for which she serves as co-investigator; d) unpacking vaccine hesitancy among perinatal healthcare providers: influences on beliefs and practices for which she serves as on co-investigator. This interest was assessed as non-personal, non-specific and financially significant\*.
- Her institution<sup>1</sup> receives research support from the Canadian Immunization Research Network to conduct studies on a) identifying effective communication materials to enhance vaccine acceptance for which she serves as co-investigator; and b) enhancing HPV vaccine uptake in school-based programs in Canada for which she serves as co-investigator. This interest was assessed as non-personal, non-specific and financially significant\*.
- Her institution<sup>1</sup> receives research support from the Nova Scotia Health Research
  Foundation to conduct studies on "An Examination of Vaccination Rates and Related
  Factors in Children and Adolescents with Autism Spectrum Disorder in Nova Scotia" for
  which she serves as co-investigator. This interest was assessed as non-personal, nonspecific and financially significant\*.
- Her institution<sup>1</sup> receives research support from the Public Health Agency of Canada to conduct a study on an environmental scan of public health recommendations for offlabel use of vaccines for which she serves as co – principal investigator.
- Her institution<sup>1</sup> receives research support from the Public Health Agency of Canada in collaboration with the Society Obstetricians and Gynecologists to conduct a study that will develop vaccine product monograph language that support evidence-based use of vaccines in maternal immunization programs for which she serves as co – principal investigator.
- Her institution<sup>1</sup> receives research support from the Public Health Agency of Canada through the Canadian Public Health Association for creation of Canadian Immunization Resource Centre for which she serves as one of two project collaborator leads.

#### Terence Nolan:

- His institution<sup>2</sup> received research support from 2013 to 2016 to conduct a
   Meningococcal ACWY vaccine clinical trial from GSK. This interest was assessed as nonpersonal, non-specific and financially significant\*.
- His institution<sup>2</sup> 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\*.
- Served on a GlaxoSmithKline (GSK) Pertussis Scientific Advisory Board, London in March 2014. This interest was assessed as non-personal, specific and financially significant\*.
- His institution<sup>2</sup> received research support in 2015 from GSK and Novartis to conduct a study on Meningococcal B vaccine. This interest was assessed as non-personal, nonspecific 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\*.

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<sup>&</sup>lt;sup>2</sup> Melbourne School of Population Health

- His institution<sup>2</sup> received research support from 2015 to 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.\*
- 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 personal, non-specific and financially significant\*.
- His institution<sup>2</sup> received research support from GSK from 2015-2017 to conduct a study in pregnant women and their offspring on Diphtheria-Tetanus-Acellular Pertussis (DTaP) vaccine. This interest was assessed as non-personal, non-specific and financially significant\*.
- Contributed to the Bionet Asia pertussis symposium in Bangkok in January 2017. This interest was assessed as non-personal, non-specific and financially insignificant\*.
- Received economy airfare and hotel accommodation and coherence registration to
  present poster at the IDWeek Scientific conference from GSK in October 2017 on clinical
  trial on which he was CI of Meningococcal B Vaccine Safety antibody persistence. This
  interest was assesses as personal, non-specific and financially significant.\*
- His institution<sup>2</sup> receives (2015-2019) research support 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 institution<sup>2</sup> receives (2016-2019) research support from Novavax to participate in a large multicenter randomized controlled trial (RCT) of a Respiratory Syncytial Virus Fusion protein (RSV-F) experimental vaccine administered to pregnant women. He participated in an investigator initiation and training meeting for the trial. This interest was assessed as non-personal, non-specific and financially significant\*.
- Serves as Chair of the Statens Serum Institute Data Safety Monitoring Board (DSMB) on adjuvanted low-dose In-activated polio vaccine (IPV). This interest was assessed as personal, non-specific and financially insignificant\*.
- His institution<sup>2</sup> receives (2016-2019) research support from Novavax to conduct a research study on RSV vaccine in pregnancy. This interest was assessed as non-personal, non-specific and financially significant\*.
- Serves as principal investigator for a clinical trial assessing cell-based quadrivalent influenza vaccine compared to Meningococcal group ACWY (MenACWY) vaccine in children funded by SEQIRUS. 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 Meningococcal Quadrivalent Tetanus Toxoid Conjugate Vaccine (MenACWY-TT) funded by GSK and Murdoch Children's Research Institute. This interest was assessed as non-personal, non-specific and financially significant\*.

#### Kate O'Brien:

- Serves as technical expert consultant for Astellas Pharma, Sutrovax, Merck, ClearPath, Affinivax and PATH on pneumococcal vaccination. This interest was assessed as nonpersonal, non-specific and financially insignificant\*.
- Serves as technical expert consultant for Sanofi Pasteur on RSV. 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 until 2014. This interest was assessed as personal, specific and financially significant\*.
- Received funding for travel costs for a GSK Grand Convergence Meeting in 2015. This interest was assessed as personal, non-specific and financially insignificant\*.

- Her institution<sup>3</sup> receives research grants from the National Institutes of Health (NIH)
  regarding pneumococcal epidemiology and vaccines, forecasting pneumococcal
  serotypes and adult vaccines. This interest was assessed as non-personal, non-specific
  and financially significant\*.
- Her institution<sup>3</sup> received research grants from the National Institutes of Health (NIH) regarding PCV13 until 2016. This interest was assessed as non-personal, non-specific and financially significant\*.
- Her institution<sup>3</sup> receives research grants from Pfizer regarding adult nasopharyngeal specimen, PCV impact evaluations and monitoring of routine immunization coverage. This interest was assessed as non-personal, non-specific and financially significant\*.
- Her institution<sup>3</sup> received research grants from Pfizer Foundation regarding monitoring of routine immunization coverage in Pakistan until June 2017. This interest was assessed as non-personal, non-specific and financially significant\*.
- Her institution<sup>3</sup> receives research grants from The Bill and Melinda Gates Foundation (BMGF) regarding pneumonia etiology, immune biomarkers of vaccination status, technical support for PCV impact, vaccine coverage, accelerating rotavirus introductions, sustaining access to vaccines in India, evaluating SMS messaging for immunization in Nigeria. This interest was assessed as non-personal, non-specific and financially significant\*.
- Her institution<sup>3</sup> received research grants from BMGF regarding disease surveillance, country support of pneumococcal and rotavirus vaccines, vaccine demand approaches, technical country support and decision making on pneumococcal/rotavirus vaccine, PCV policy optimization and pneumococcal, Hib and meningococcus etiology work (disease burden estimates) until 2015. This interest was assessed as non-personal, non-specific and financially significant\*.
- Her institution<sup>3</sup> received research grants from BMGF regarding technical support on pneumococcal disease and rotavirus in India until 2017. This interest was assessed as non-personal, non-specific and financially significant\*.
- Her institution<sup>3</sup> received research grants from Gavi regarding PCV and rotavirus vaccine, scientific communication support, PCV product assessment and strengthening routine immunization and vaccine delivery platforms in Nigeria until 2017. This interest was assessed as non-personal, non-specific and financially significant\*.
- Her institution<sup>3</sup> received research grants from Merck regarding adult vaccination and the value of adult vaccine preventable diseases until 2016. This interest was assessed as non-personal, non-specific and financially significant\*.
- Her institution<sup>3</sup> received research grants from Pfizer regarding PCV impact evaluation in India until 2017. This interest was assessed as non-personal, non-specific and financially significant\*.
- Her institution<sup>3</sup> receives research grants from the John Snow Institute (JSI) Research & Training Institute, Inc. regarding programmatic impact of multi-dose vaccines. This interest was assessed as non-personal, non-specific and financially significant\*.
- Her institution<sup>3</sup> receives research grants from Oxford and Gavi regarding assessing PCV impact in Nepal. This interest was assessed as non-personal, non-specific and financially significant\*.

<sup>&</sup>lt;sup>3</sup> International Vaccine Access Centre, Johns Hopkins Bloomberg School of Public Health, United States of America

# **Andrew Pollard:**

- His institution<sup>4</sup> received research support until 2014 from GSK on Pneumococcal vaccine.
   This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution<sup>4</sup> received research support until 2014 from Novartis on Meningococcal B vaccine. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution<sup>4</sup> received research support until 2016 from Okairos on RSV vaccine. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution<sup>4</sup> 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 institution<sup>4</sup> received research support on a grant for a study on the cause of fever with Bexsero funded by a European Commission grant (EUCLIDS; funding 2011-2017).
   The vaccine for the study is provided by Novartis/GSK. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution<sup>4</sup> received research support on a grant for a study on the efficacy of a typhoid vaccine (Typbar-CV) produced by Bharat Biotech, India (2013-2016). No funding was received from Bharat Biotech, the grant was funded by BMGF. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution<sup>4</sup> 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 institution<sup>4</sup> 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 institution<sup>4</sup> 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 institution<sup>4</sup> received unrestricted educational grants from Novartis/GSK/Astra
  Zeneca/Sanofi Pasteur MSD (SPMSD) in 2014; Novartis/GSK/Astra Zeneca in 2015 and
  Pfizer/GSK/Astra Zeneca in 2016 and from Gilead/MSD/GSK/Astra Zeneca in June 2017
  for a course on infection and immunity in children. This interest was assessed as nonpersonal, non-specific and financially significant\*.
- His institution<sup>4</sup> received research support until 2014 from SPMSD on a hexavalent infant vaccine. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution<sup>4</sup> receives research support on a grant for a study 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 institution<sup>4</sup> receives research support on a grant for a study on pertussis vaccines funded by a European Commission grant (PERISCOPE, 2016-current). This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution<sup>4</sup> receives research support on a grant for a study pneumococcal pneumonia and carriage by a European Commission Horizon 2020 grant (2016-2020).
   This interest was assessed as non-personal, non-specific and financially significant\*.

<sup>&</sup>lt;sup>4</sup> Paediatric Infection and Immunity, University of Oxford, United Kingdom

- His institution<sup>4</sup> receives grants from Innovate UK for plague and Q fever vaccines (2016-2019). This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution<sup>4</sup> receives a grant from Meningitis Research Foundation to study Bexsero in teenagers (2018-current) and MRC to study novel meningococcal vaccine in phase I.
   This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution<sup>4</sup> receives (2018-current) a grant from the Medical Research Council to study novel meningococcal vaccine in phase I. This interest was assessed as non-personal, non-specific and financially significant\*.

#### Nikki Turner:

- Her institution<sup>5</sup> received a research grant from GSK for an effectiveness trial of the pneumococcal conjugate 10 vaccine (PCV10). This interest was perceived as nonpersonal, non-specific and financially significant\*.
- Her institution<sup>5</sup> 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 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 she serves as director, ran a national immunisation conference in September 2015 with sponsorship from GSK, Mylan EPD, Sanofi, Pfizer, Pharmac, 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\*.
- The Immunisation Advisory Centre, for which she serves as director, organized a
  national influenza symposium in November 2016 with sponsorship from GSK, Mylan EPD
  and Sequris towards the cost of running the symposium. 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 insignificant\*.
- The Immunisation Advisory Centre, for which serves as director, organized the New Zealand Immunisation Conference in September 2017 with sponsorship from GSK, Mylan EPD, Green Cross Health, Rollex Medical, Bell Technology, Sanofi Pasteur and Sequris towards the cost of running the conference. None of the sponsors had input to the conference planning or setting of the programme. Sponsors had stands at the conference. This interest was assessed as non-personal, non-specific and financially significant\*.
- The Immunisation Advisory Centre, ran a New Zealand national influenza symposium on 8 February 2018, this included accepting sponsorship from Pharmaceutical companies, Sanofi Pasteur, Mylan, Seqirus. None of the speakers were funded and the sponsorship had no involvement in the setting of the programme. This interest was assessed as nonpersonal, non-specific and financially insignificant\*.

# 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\*.

<sup>&</sup>lt;sup>5</sup> Immunisation Advisory Centre, University of Auckland, New Zealand

- Serves on the PATH advisory board for the whole cell pneumococcal vaccine until 2018. This interest was assessed as non-personal, non-specific and financially insignificant\*.
- Serves as principal investigator for a trial on fractional dose use of PCV sponsored by the BMGF through the Wellcome Trust Kenya. This interest was assessed as non-personal, non-specific and financially significant\*.
- Serves as member of a DSMB for fractional dose use of yellow fever vaccine in Kenya sponsored by Epicentre through Médecins Sans Frontières (MSF) France. This interest was assessed as non-personal, non-specific and financially significant\*.

# **Charles Wiysonge:**

 Served as the principal investigator for the SIVAC Initiative at the Agence de Médecine Preventive (AMP) from May to June 2017. This interest was assessed as non-personal, non-specific and financially significant\*.

\* 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.

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

The above summary of reported interests was made available for public notice and comment on the WHO SAGE website prior to the October 2017 SAGE meeting. No comments have been received.