

**Meeting of Strategic Advisory Group of Experts (SAGE)  
on Immunization**

**08-10 October 2019**

**DECLARATION OF INTERESTS**

All 14 SAGE members participating in the meeting updated their declaration of interest ahead of the meeting. Nine SAGE members reported relevant interests, of which none was assessed to constitute a conflict of interest in relation to any session. It was assessed that all members could fully participate in all sessions. All the reported relevant interests are summarized below:

**Alejandro Cravioto:**

- Is member of the PREVENT working group. This interest was assessed as personal, non-specific and financially non-significant\*.

**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, 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 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\*.
- His institution has received funding from the European and Developing Country Clinical Trial Partnership (EDCTP) for a Phase IIb/III three-arm, two-stage HIV prophylactic vaccine trial with a second randomisation to evaluate the proportion of HIV infections averted by TAF/FTC in comparison to TDF/FTC pre-exposure prophylaxis (PrEPVacc) for which he will serve as a site principal investigator starting in 2020. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution received a grant/research support from WHO to conduct a study aiming at comparing the immunogenicity of one drop vs two drops OPV during a cVDPV outbreak and to conduct a study to evaluate the safety and immunogenicity of fIPV delivered i.m. This interest was assessed as non-personal, specific and financially significant\*.

**Firdausi Quadri:**

- Served until December 2017 as principal investigator for a randomized, placebo-controlled trial to measure the protection conferred by a single dose regimen of bivalent, killed, whole cell oral cholera vaccine (Shanchol) in Dhaka, Bangladesh funded by the International Vaccine Institute and the Bill and Melinda Gates Foundation. This interest was assessed as non-personal, non-specific and financially significant\*.

- Served until September 2017 as principal investigator for a phase I/II dose-escalation study to evaluate safety, tolerability and immunogenicity of '2-dose primary series' single strain (Hikojima serotype) inactivated Oral Cholera Vaccine formulations funded by MSD, Wellcome Trust and Hilleman Laboratories. This interest was assessed as non-personal, non-specific and financially significant\*.
- Served until September 2017 as a co-principal investigator for a randomized observer blinded controlled non inferiority trial to evaluate the safety and immunogenicity of locally manufactured inactivated bivalent whole cell-oral cholera vaccine (WC-OCV) 'Cholvax' in Bangladeshi healthy adults and children funded by the International Vaccine Institute and the Bill and Melinda Gates Foundation. This interest was assessed as non-personal, non-specific and financially significant\*.
- Served until October 2017 as principal investigator on a trial to assess a cost-effective and impactful strategy for deploying oral cholera vaccine in children in urban slums in Bangladesh funded by Gavi, the Vaccine Alliance. This interest was assessed as non-personal, non-specific and financially significant\*.
- Serves as a principal investigator for a trial evaluating the introduction of cholera vaccine in Bangladesh funded by the Bill and Melinda Gates Foundation. This interest was assessed as non-personal, non-specific and financially significant\*.
- Serves as a principal investigator for a trial 'A Phase I, Double-Blinded, Placebo-Control Dose Escalating Study to Evaluate the Safety and Immunogenicity of Double Mutant Heat-Labile Toxin STR192G/L211A (dmlT) from ETEC by Oral, Sublingual, or Intradermal Vaccination in Adults Residing in an Endemic Area' project through University of Maryland funded by NIH. This interest was assessed as non-personal, non-specific and financially significant\*.
- Serves as a principal investigator for a trial "Cholera serosurveys to refine estimates of burden and population at risk," sub-award by 'The Johns Hopkins University' prime donor is BMGF. The purpose of this grant is to improve incidence estimates of the global cholera burden and the size of the global population at-risk for cholera infection and to pioneer the use of new methods to measure the impact of cholera prevention and control tools, such as OCV. This interest was assessed as non-personal, non-specific and financially significant\*.
- Serves as a principal investigator for a study 'Oral cholera vaccination campaign among the Rohingya Myanmar Nationals in Bangladesh to assess the effectiveness' funded by UNICEF. This interest was assessed as non-personal, non-specific and financially significant\*.
- Serves as a principal investigator for a trial 'Assessing the impact of a Vi-Polysaccharide Conjugate Vaccine in preventing typhoid infection among Bangladeshi children – a Phase IIIb trial'. Project through University of Oxford, prime donor BMGF. This interest was assessed as non-personal, non-specific and financially significant\*.
- Serves as a principal investigator for a trial 'A strategic vision to drive the control of enteric fever through vaccination' project through University of Oxford, prime donor BMGF and University of Oxford. This interest was assessed as non-personal, non-specific and financially significant\*.

**Noni MacDonald:**

- Serves as consultant for WHO in regard to Environmental Scan of National Immunization Technical Advisory Group (NITAG) and Immunization Program Legislation and Governance. This interest was assessed as personal, non-specific and financially significant\*.
- Serves as a Co-Investigator on a study for the Social Sciences and Humanities Research Council on The nature and extent of vaccine hesitancy among chiropractors and

- naturopaths: identifying how vaccination views impact practice (2018-2022). This interest was assessed as non-personal, non-specific and financially significant\*.
- Served in 2018 as a supervisor on a study for WHO on Analysis and updating of Vaccine Hesitancy Joint Reporting Form data 2014- 2017. This interest was assessed as personal, non-specific and financially significant\*.
  - Served as consultant in regard to vaccine-related issues (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\*.
  - Serves as consultant for WHO regional offices on different immunization program issues. This interest was assessed as personal, non-specific and financially insignificant\*.
  - Her institution 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 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\*.
  - Her institution 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 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 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, non-specific and financially significant\*.
  - Her institution receives research support from the Public Health Agency of Canada to conduct a study on an environmental scan of public health recommendations for off-label use of vaccines for which she serves as co – principal investigator. This interest was assessed as non-personal, non-specific and financially significant\*.
  - Her institution 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. This interest was assessed as non-personal, non-specific and financially significant\*.

- Her institution 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. This interest was assessed as non-personal, non-specific and financially significant\*.
- Her institution receives research support from Academics Without Borders as well as Rotary Club on for MicroResearch, a program for community focused research capacity building in Africa and in Nova Scotia. This interest was assessed as non-personal, non-specific and financially significant\*.

**Shabir Madhi:**

- Serves as a member of the International Vaccine Institute (IVI) Scientific Advisory Committee. This interest was assessed as non-personal, non-specific and financially insignificant\*.
- Serves as a member of the BMGF Global Health Scientific Advisory Committee. This interest was assessed as non-personal, non-specific and financially significant\*.
- Served as advisor to the Pfizer Group B streptococcal (GBS) vaccine program until 2017. This interest was assessed as non-personal, non-specific and financially insignificant\*.
- Serves as a member of the DSMB of GSK on porcine-free rotavirus vaccine. This interest was assessed as non-personal, non-specific and financially insignificant\*.
- Serves as a member of the DSMB of Janssen on inactivated polio vaccine. This interest was assessed as non-personal, specific and financially insignificant\*.
- Serves as a member of the DSMB of CAPRISA on a HIV monoclonal antibody. This interest was assessed as non-personal, non-specific and financially insignificant\*.
- His institution receives grants from Pfizer on a GBS vaccine clinical trial and GBS epidemiology study on correlate of protection. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution received grants from Novartis and GSK support on GBS epidemiology until 2017. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution receives grants from BMGF on epidemiology studies of GBS and pneumococcus, and clinical trials on PCV. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution received a grant from VPM /Serum Institute regarding a clinical trial on tuberculosis until 2017. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution received a grant from Medimmune regarding clinical trials on RSV monoclonal antibody until 2017. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution receives a grant from Novovax regarding a clinical trial on maternal RSV vaccine program. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution receives a grant from Mitsubishi regarding a clinical trial on rotavirus vaccine. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution will receive a grant from MSD in February 2019 regarding a clinical trial on monoclonal RSV antibody. This interest was assessed as non-personal, non-specific and financially significant\*.

**Kathy Neuzil:**

- Serves as a member of the Board of Directors for the US National Foundation of Infectious Diseases. This interest was perceived as non-personal, non-specific and financially insignificant\*.
- Serves as co-investigator on an NIH contract for a Vaccine and Treatment Evaluation Unit. As part of this contract, she is principal investigator for 3 studies: A trial of Tdap among pregnant women in Mali, clinical studies of H7N9 influenza vaccines among U.S. adults, and clinical study of H5N8 vaccine among U.S. adults. This interest was perceived as non-personal, non-specific and financially significant\*.
- Serves as principal investigator for the Bill and Melinda Gates Foundation-funded Typhoid Vaccine Acceleration Consortium (2016-2021), which includes clinical studies of Bharat Biotech, India Tybbar-TCV. This interest was perceived as non-personal, non-specific and financially significant\*.
- Served as the IDSA liaison representation to the U.S. CDC Advisory Committee on Immunization Practices from 2010-December 31, 2018. This interest was perceived as non-personal, non-specific and financially insignificant\*.
- Served as a co-investigator on a study of polyvalent meningococcal vaccine manufactured by Serum Institute of India, Ltd. (SIIL) in 2017 and 2018. This interest was perceived as non-personal, non-specific and financially significant\*.
- Her institution receives research support for the following studies. These interests were perceived as non-personal, non-specific and financially significant\*.
  - A grant award from Nosocomial Vaccine Company for development of novel vaccines for multidrug-resistant gram-negative bacteria and for production and purification of Staphylococcus aureus type 5 and 8 capsule polysaccharides.
  - Safety and reactogenicity of HTNV, PUUV, and combination HTNV/PUUV DNA vaccine from Geneva Foundation
  - Phase 3A study of human rotavirus vaccine vaccine in healthy infants 6-12 weeks of age (ROTA-090) from GSK.
  - Double-Blind, Randomized, Placebo-Controlled Phase 2b Study to Evaluate the Safety, Tolerability, Efficacy, and Immunogenicity of a 2-Dose and 3-Dose Regimen of V160, Human Cytomegalovirus (HCMC) Vaccine in Healthy Seronegative Adolescent and Adult Women 16-35 Years of Age funded by Merck.
  - A Phase III, Stratified, Randomized, Observer Blind, Controlled, Multicenter Clinical Study to Evaluate the Safety, Immunogenicity and Efficacy of an Adjuvanted Quadrivalent Subunit Influenza Virus Vaccine Compared to Non-Adjuvanted Comparator Influenza Vaccine in Children > 6 to < 72 Months of Age funded by ICON clinical Research, and ended in 11/16.
- Her institution received research support for the following studies:
  - A grant from Bill and Melinda Gates Foundation to study influenza vaccine in pregnant women in Mali. (grant ended 2017).These interests were perceived as non-personal, non-specific and financially significant\*.
- Her institution received research support for a phase 2 safety and immunogenicity study of GSK recombinant chimpanzee adenovirus Ebola vaccine (grant ended 2/2017). This interest was perceived as non-personal, specific and financially significant\*.
- Her institution receives research support for a study on safety and immunogenicity of GSKs' Rabies SAM (CNE) vaccine (GSK3903133A) in healthy adults (funded by GSK). This interest was perceived as non-personal, specific and financially significant\*.

**Andrew Pollard:**

- His institution received research support until 2016 from Okairos on RSV vaccine. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution 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 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 received in 2018 research support from MRC on paratyphoid vaccine (University of Maryland). This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution 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 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 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 received unrestricted educational grants from Pfizer/GSK/Astra Zeneca in 2016, from Gilead/MSD/GSK/Astra Zeneca in June 2017 and from Gilead/Sanofi Pasteur/GSK/Astra Zeneca in June 2018 and from GSK and Gilead in July 2019 for a course on Infection & Immunity in Children. This interest was assessed as non-personal, non-specific and financially significant\*.
- Serves as investigator for a study on Ebola vaccine developed by Janssen (2015-current) funded by a European Commission IMI grant (EBOVAC). This interest was assessed as non-personal, specific and financially significant\*.
- His institution 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 receives research support on RSV biomarkers funded by a European Commission grant (RESCEU 2016-current). This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution receives research support on a grant for a study on 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\*.
- His institution 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 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 receives (2018-current) a grant from the BMA on RSV. This interest was assessed as non-personal, non-specific and financially significant\*.

- Serves as chair of UK Department of Health's Joint Committee on Vaccines and Immunization and as chair of the EMA Scientific Advisory Group on Vaccines (SAG-V). This interest was assessed as non-personal, non-specific and financially insignificant\*.
- Serves on the Wellcome Trust Hilleman Laboratories scientific advisory committee. This interest was assessed as non-personal, non-specific and financially insignificant\*.

**Nikki Turner:**

- Her institution received a research grant in 2016 from GSK for an observational trial of the pneumococcal conjugate 10 vaccine (PCV10). This interest was perceived as non-personal, non-specific and financially significant\*.
- Her institution received a research grant in 2016 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, 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, for which serves as director, will organize the New Zealand Immunisation Conference in September 2019 with sponsorship from Sanofi, GSK, Sequris, Green Cross Health, Rollex Medical, Bell Technology, Temprecord, Pfizer, Merck and Butler Sense. 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 and 21 February 2019, 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 non-personal, non-specific and financially insignificant\*.

**Fred Were:**

- Serves as a member of the MSD European Vaccines Advisory board (2018-2019). This interest was assessed as non-personal, non-specific and financially significant\*.
- 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 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\*.

\* 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". As per WHO assessment of conflicts of interests, "Institution" relates only to the expert's research/or work unit, as subdivision of the department. Funding going to the SAGE member's research unit needs to be declared.

The above stated conflicts has been made available for public notice and comment 4 weeks prior to the SAGE meeting in order to provide information on interests or biases relating to potential conflicts of SAGE members. No comments were received.