

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

3-6 October 2022

DECLARATION OF INTERESTS

All 15 SAGE members participating in the meeting updated their declaration of interest ahead of the meeting. 11 SAGE members reported relevant interests. Kathy Neuzil and Punnee Pitisuttithum recused themselves from the recommendation making regarding COVID-19, whereas Shabir Madhi has recused himself from recommendation making regarding COVID-19 vaccine and RSV vaccine session, and likewise Illesh Jani recused himself from recommendation making regarding Ebola and COVID-19 vaccine session. It was assessed that the remaining members could fully participate in the meeting.

All the reported relevant interests are summarized below:

Rakesh Aggarwal:

- Serves as advisory to the National Technical Advisory Group (NITAG) of India. This interest was assessed as non-personal, non-specific and financially insignificant*.

Illesh 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 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*.
- 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 randomization 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 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*.

- Served as investigator for the OPV 1 vs 2 phase II funded by WHO. This interest was assessed as non-personal, specific and financially significant*.
- Serves as supervisor for the OPV phase II trial funded by WHO. This interest was assessed as non-personal, specific and financially significant*.
- Served on the Covid-19 vaccine trial funded by Sanofi. This interest was assessed as non-personal, specific and financially significant*.
- Serves as principal investigator on Covid-19 vaccine trials funded by CEPI and BMGF. This interest was assessed as non-personal, specific and financially significant*.
- His institution received a grant/research support from WHO to conduct an observational study on nOPV. This interest was assessed as non-personal, specific and financially significant*.

Noni MacDonald:

- Serves on the South Korea Scientific Advisory Committee of the International Vaccine Institute. This interest was assessed as non-personal, non-specific and financially insignificant*.
- Serves on the Curevac Reg Advisory Committee. This interest was assessed as non-personal, specific and financially insignificant*.
- Serves on the Board of the Australian National Center for Immunization Research and Surveillance. This interest was assessed as non-personal, non-specific and financially insignificant*.
- Her institution received a grant from Vaccine hesitancy Consultancy, Merck, This interest was assessed as non-personal, non-specific and financially insignificant*.
- Serves as consultant for WHO in regard to Environmental Scan of NITAG and Immunization Program Legislation and Governance. This interest was assessed as non-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*.
- 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 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 Clubon 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*.
- Her institution receives a grant from the Canadian Institutes of Health Research to conduct studies on sociocultural and behavioural factors affecting communities’s response to countermeasures for Covid-19 epidemic. This interest was assessed as non-personal, specific and financially significant*.
- Her institution receives a grant from the Canadian Institutes of Health Research for Covid-19 rapid research FO – social policy and public health responses. This interest was assessed as non-personal, specific and financially significant*.
- Her institution receives a grant from the Canadian Institutes of Health Research for Covid-19 Legal Frameworks for Vaccination Research Rapid Response. This interest was assessed as non-personal, specific and financially significant*.
- Her institution receives a grant from the Canadian Institutes of Health Research for Covid-19 Vaccine Readiness. This interest was assessed as non-personal, specific and financially significant*.

Shabir Madhi:

- Served until 2019 as 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*.
- 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 Chair 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 receives grants from BMGF on epidemiology studies of GBS and pediatric pneumococcus, and clinical trials on pediatric PCV. Role: National Principal Investigator. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution receives a grant from Novavax regarding a clinical trial on maternal RSV vaccine program. This interest was assessed as non-personal, 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 received a grant from MSD in February 2019 regarding a clinical trial on monoclonal RSV antibody. This interest was assessed as non-personal, specific and financially significant*.
- His institution receives funds from BMGF for the conduct of COVID-19 epidemiology studies. This interest was assessed as non-personal, specific and financially significant*.
- Serves as National Principal Investigator on a phase II study on ChAdOx-nCoV19 (University of Oxford) vaccine. This interest was assessed as non-personal, specific and financially significant*.
- Serves as National Principal Investigator on a Phase II study on Novavax COVID-19 vaccine funded by BMGF and Novavax. This interest was assessed as non-personal, specific and financially significant*.
- Serves on the Clinical-Regulatory Advisory Board of CureVac for Covid-19 vaccine. This interest was assessed as non-personal, specific and financially insignificant*.

Peter McIntyre :

- Serves as a member of the DSMB for the Novavax Covid-19 vaccine. This interest was assessed as non-personal, specific and financially insignificant*.
- Serves as a member of the New Zealand TAG on Meningococcal and Measles vaccines. This interest was assessed as non-personal, non-specific and financially insignificant*.
- Serves as a member of the New Zealand Scientific and TAG on COVID-19 vaccines. This interest was assessed as non-personal, specific and financially insignificant*.
- Serves as investigator on Wellcome Trust grant: “Effectiveness of vaccines to prevent antibiotic prescribing for acute respiratory tract infections in high-risk adults” based on a proposed study of vaccine and antibiotic prescribing data on a large Australian primary care database. This interest was assessed as non-personal, non-specific and financially significant*.
- Serves as investigator on Australian Indo-Pacific Centre research grant: “Mitigating health security risks by supporting immunisation coverage and preventing outbreaks”. This interest was assessed as non-personal, non-specific and financially significant*.
- Serves as investigator on National Health and Medical Research Council Project Grant: Assessing acellular pertussis vaccine effectiveness: integrating

transmission models, genetics and cohort data to inform policy. This interest was assessed as non-personal, non-specific and financially significant*.

- Serves as investigator on National Health and Medical Research Council Project Grant: Quantifying the effectiveness of pertussis vaccine in older adults. This interest was assessed as non-personal, non-specific and financially significant*.
- Serves as investigator on National Health and Medical Research Council Partnership Grant: Reducing vaccine preventable diseases in children: using national active hospital-based surveillance to evaluate and improve immunisation program performance. This interest was assessed as non-personal, non-specific and financially significant*.
- Serves as investigator on National Health and Medical Research Council Project Grant: Economic evaluation of alternative pneumococcal vaccination strategies. This interest was assessed as non-personal, non-specific and financially significant*.
- Serves as investigator on National Health and Medical Research Council Project Grant: Vaccination timeliness in Aboriginal and non-Aboriginal infants: risk factors for delayed vaccination and impact on disease burden – a record linkage study. This interest was assessed as non-personal, non-specific and financially significant*.
- Serves as investigator National Health and Medical Research Council Centre for Research Excellence: Accelerating introduction of pneumococcal conjugate vaccines in the Asia-Pacific region. This interest was assessed as non-personal, non-specific and financially significant*.
- Serves as lead investigator on Otago Medical Research Foundation Grant NZ : Immunity to measles in young adults: is it waning and does it matter?“. This interest was assessed as non-personal, non-specific and financially significant*.

Kim Mulholland:

- Serves as principal investigator on Covid-19 fractional boosting funded by Cepi. This interest was assessed as non- personal, specific and financially significant*.
- Serves as collaborative member of a observational study of adult pneumonia in Mongolia, which is designed to inform an area of public health that is generally neglected in LMICs funded by Pfizer. This project is led by a member of my group. This interest was perceived as non-personal, non-specific and financially insignificant*.
- Serves as principal investigator on Vietnam pneumococcal vaccine trials 1 and 2 funded by the Bill and Melinda Gates Foundation. This interest was assessed as non- personal, non-specific and financially significant*
- Serves as principal investigator on an evaluation of PCV schedule in a naïve population in Vietnam funded by the Bill and Melinda Gates Foundation. This interest was assessed as non- personal, non-specific and financially significant*.
- Serves as principal investigator until 2022 on the evaluation of the impact of PCV in Mongolia funded by GAVI. This interest was assessed as non- personal, non-specific and financially significant*.
- Served as Novavax DSMB for Covid-19 vaccine trials in Australia and South Africa. This interest was perceived as non-personal, specific and financially insignificant* ceased: 2022
- Served as principal investigator until 2022 on the evaluation of the impact of PCV in Mongolia funded by GAVI. This interest was assessed as non- personal, non-specific and financially significant*.

- Served as principal investigator until 2019 on HPV detection in young women 5 years following the 4-valent HPV vaccine in Mongolia funded by the Bill and Melinda Gates Foundation. This interest was assessed as non- personal, non-specific and financially significant*.
- Advised Allens Law Firm on pneumococcal conjugate vaccine issues. The task was to educate lawyers on the details of PCVs and pneumococcal disease. This interest was perceived as personal, non-specific and financially significant* Ceased 2018
- Served as Chair of DSMB until 2018 for phase 3 trials of PCV10 in Gambia. This interest was assessed as personal, non-specific and financially insignificant*.

Kathleen 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 PI for NIH-funded Collaborative Influenza Vaccine Innovation Center (CIVICs) program. This interest was perceived as non-personal, non-specific and financially significant*.
- 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, and an influenza challenge study. 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 and extension 2021-2025),, which includes clinical studies of Bharat Biotech, India Typhbar-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*.
 - Safety and reactogenicity of HTNV, PUUV, and combination HTNV/PUUV DNA vaccine from Geneva Foundation
 - 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.
- Serves as an investigator on a grant from University of Washington for a COVID-19 post-exposure prophylaxis study of hydroxychloroquine. This interest was perceived as non-personal, specific and financially significant*.

- Co-chair of the NIH COVID Vaccine Prevention Network, which serves as the focal point for USG sponsored trials in COVID-19 vaccines and monoclonal antibodies. This Network is supported through an NIH grant for the leadership of the Vaccine Treatment and Evaluation Units. This interest was perceived as non-personal, specific and financially significant*.
- Serves as principal investigator for the NIAID/NIH funded Advanced Development of a Multivalent Vaccine Candidate for Filovirus and Lassa Fever. This interest was perceived as non-personal, non-specific and financially significant*.
- Serves as principal investigator for the NIH funded NIH T32 Fellowship Training Program in Vaccinology . This interest was perceived as non-personal, non-specific and financially significant*.

Hanna Nohynek

- Her institution (Finnish Institute for Health and Welfare) has been receiving research grants from vaccine manufacturers for phase III and IV pediatric pneumococcal vaccine evaluations. This interest was assessed as non-personal, non-specific and financially significant*.
- Her institution (Finnish Institute for Health and Welfare) has been receiving research grants from vaccine manufacturers for phase III and IV studies of influenza vaccines. This interest was assessed as non-personal, non-specific and financially significant*.
- Serves as secretary of the THL NITAG and in that position needs to give public statements on NITAG decisions / recommendations, and she has also served as expert to European Medicines Agency (EMA) and Finnish Medicines Agency (Fimea) from those grounds. This interest was perceived as non-personal, non-specific and financially insignificant*.
- Serves as secretary of Finnish NITAG which makes recommendations on use of covid-19 vaccines. This interest was perceived as non-personal, specific and financially insignificant*.
- Serves as Chief physician in charge of advising Finnish MoH on the matter and giving advice to the Finnish professionals dealing with covid-19 vaccinations. This interest was perceived as non-personal, specific and financially insignificant*.
- Serves as investigator in an Innovative Medicines Initiative (IMI) funded project DRIVE (Development of Robust and Innovative Vaccine Effectiveness) 2018-23. This interest was perceived as non-personal, non-specific and financially insignificant*.
- Serves as Chair of the DSMB of an IMI funded PERISCOPE study on maternal pertussis immunization in the Gambia. This interest was perceived as non-personal, non-specific and financially insignificant*.
- Serves as a member of the research group validating the methodology used of the Effectiveness (I-MOVE+)) (2015-2018) and the European Centre for Disease Prevention and Control (ECDC) (I-MOVE) (2016-2017) network measuring effectiveness of influenza vaccination in the EU context. This interest was assessed as non-personal, non-specific, and financially insignificant*.
- Serves as member to DSMB of COMCov studies of University of Oxford. This interest was assessed as non-personal, specific and financially insignificant*.
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Folake Olayinka:

- Serves as advisor to the WHO-AFRO Regional Immunization Technical Advisory Group. This interest was perceived as non-personal, non-specific and financially insignificant*.
- Serves as Scientific Advisor to the African Local Initiative for Vaccinology Expertise Scientific Advisory Group. This interest was perceived as non-personal, non-specific and financially insignificant*.

Punnee Pitisuttithum:

- Serves on the Safety Monitoring Committee for the U.S. Military HIV Research Program (MHRP). This interest was perceived as non-personal, non-specific and financially insignificant*.
- Serves as principal investigator for the GPO-funded phase III to Evaluate the Immunogenicity and Safety of Tri Fluvac influenza vaccine. This interest was perceived as non-personal, non-specific and financially significant*.
- Serves as principal investigator for the National Science and Technology Development Agency-funded phase II/III combined Diphtheria-Tetanus-recombinant acellular pertussis (DTaP) vaccine to a licensed DTaP based vaccine (non-recombinant). This interest was perceived as non-personal, non-specific and financially significant*.
- Serves as principal investigator for the MSD-funded phase III Study the Efficacy, Immunogenicity, and Safety of the 9vHPV vaccine. This interest was perceived as non-personal, non-specific and financially significant*.
- Serves as principal investigator for the government funded phase I/II study of the NDV-HXP-S Covid vaccine. This interest was perceived as non-personal, specific and financially significant*.
- Serves as principal investigator coordinator for the government funded study of the immunogenicity and safety of the 3rd dose of the ChAdOx-nCoV19 or BNT162b2 vaccine against COVID19 vaccine. This interest was perceived as non personal, specific and financially insignificant*.
- Serves as principal investigator for the Janssen funded phase I/II study of the immunogenicity and safety of the Ad26.CoV2.S heterologous against COVID19 vaccine. This interest was perceived as non-personal, specific and financially significant*.

Anthony Scott:

- Served until 2020 on the DSMB of PATH Vaccine Solutions, Clinical development of Pneumosil. Vaccine trial in Gambia . This interest was assessed as non-personal, non-specific and financially insignificant*.
- Served on the DSMB of Iliad Biotechnologies, Phase 2b trial of Intranasal Pertussis vaccine BPZE1. This interest was assessed as non-personal, non-specific and financially insignificant*.
- Serves on the UK Dept of Health and Social Care Joint Committee on Vaccination and Immunisation. This interest was assessed as non-personal, non-specific and financially insignificant*.
- Served on the Expert Working Group on COVID-19 vaccine safety for the UK Commission on Human Medicines / MHRA. This interest was assessed as non-personal, specific and financially insignificant*.

- Serves as principal investigator for the BMGF funded study on fractional doses of PCV in infants in Kenya. This interest was perceived as non-personal, non-specific and financially significant*.
- Serves as co-investigator for the UK Foreign Commonwealth and development office funded study on COVID-19 vaccine evaluation in Kenya. This interest was perceived as non-personal, specific and financially significant*.
- Serves as principal investigator for the European Union funded study on Vacc-iNTS, Phase I/II trial of NTS vaccine in Kenyan adults. This interest was perceived as non-personal, non-specific and financially significant*.
 - Serves as principal investigator for the GAVI funded study on PCVIS -post-licensure study of PCV10 impact, Kenya . This interest was perceived as non-personal,non-specific and financially significant*.His institution receives research support for the following studies. These interests were perceived as non-personal, non-specific and financially significantResearch grant on cause of child death in Ethiopia (CHAMPS) from Emory University
 - Research grant on surveillance of Meningococcus in Ethiopia from BMGF
 - Research grant on using pneumococcal carriage to inform PCV policy in Africa from welcome trust
 - Research grant on developing vaccine policy within the UK from National Institute for Health Research

* 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 are 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. Comments will be treated in a confidential manner and should be e-mailed to the Secretariat (sageexecsec@who.int) at least 2 weeks ahead of the meeting.