

COVID-19 Vaccines Safety Surveillance Methodologies Expert Working Group

Remit

Pre-deployment phase

- To landscape the different healthcare datasets that are currently available in the UK to capture near real-time information on COVID-19 vaccine exposure and study endpoints relevant to vaccine safety and potential for disease enhancement (and effectiveness). This should take into account a range of potential scenarios for vaccine deployment (i.e. the point of administration and any prioritised/targeted immunisation), and should advise on the need for further data capture and linkage.
- To advise on the most suitable study endpoints and design(s) to monitor COVID-19 vaccine safety, and potential for disease enhancement (and effectiveness).
- To support engagement with UK institutions who may be planning/in a position to conduct COVID-19 vaccine safety studies. This is to encourage and facilitate studies that are complementary in terms of objective and design, to avoid duplication and to accommodate a suitable range of study endpoints and scenarios for vaccine deployment.
- To advise on proposals for enhanced passive surveillance.
- To advise on communications in support of the pharmacovigilance strategy.

Post-deployment phase

- To advise on the emerging evidence from all data sources on the risks and benefits of vaccine(s) during the course of any COVID-19 immunisation campaign in the UK. This includes measures to minimise risks, and optimise the benefit-risk balance for individual vaccines, such as any new precautions or restrictions on use.
- To advise on any communications to health professionals and the public.
- To advise on measures to monitor impact/effectiveness of any additional risk minimisation.

Chair

Dr Siraj Misbah MBBS (Hons) MSc FRCP FRCPath Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals & Chair of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG) & Member of the Commission on Human Medicines (CHM)

Members

Professor Ian J Douglas BSc MSc PhD Senior Lecturer in Pharmacoepidemiology, London School of Hygiene & Tropical Medicine & Member of the Pharmacovigilance Expert Advisory Group (PEAG)

Professor Jonathan S Friedland MA PhD FRCP FRCPE FRCPI FESCMID FMedSci Deputy Principal, St. George's, University of London & Chair of the Infections Expert Advisory Group (IEAG) & Member of the Commission on Human Medicines (CHM)

Sir Michael Jacobs MA PhD MB BS FRCP FRCP Edin DTM&H Clinical Director of Infection, Royal Free London NHS Foundation Trust & Hon. Senior Lecturer, Liverpool School of Tropical Medicine

Professor Simon De Lusignan Professor of Primary Care and Clinical Informatics, University of Oxford

Dr Rupert Payne PhD MRCP FRCPE FBPhS Consultant Senior Lecturer in Primary Care, University of Bristol & Member of the Pharmacovigilance Expert Advisory Group (PEAG)

Professor Sir Munir Pirmohamed MB ChB (Hons) PhD FRCP FRCP (Edin) FBPhS, FFPM (Hon) FMedSci David Weatherall Chair of Medicine, University of Liverpool, NHS Chair of Pharmacogenetics, Director of the Wolfson Centre for Personalised Medicine, Director of the MRC Centre for Drug Safety Science

Professor Siobhan Quenby MBBS BSc MD FRCOG Professor of Obstetrics, Warwick University & Member of the Medicines for Women's Health Expert Advisory Group (MWHEAG)

Professor Chris Robertson PhD MSc BSc Professor of Public Health Epidemiology, University of Strathclyde

Professor Calum Semple PhD FRCPCH FRCPE FHEA Professor of Outbreak Medicine University of Liverpool

Invited Experts

Professor Elizabeth Miller Department of Infectious Disease Epidemiology, Faculty of Epidemiology & Population Health, London School of Hygiene & Tropical Medicine

Professor Anthony Scott JCVI member, and Professor of vaccine epidemiology, Director HPRU in immunisation

Helen McDonald [LSHTM](#) Health Protection Research Unit

Jemma Walker [LSHTM](#) Health Protection Research Unit

Observers

Professor Liam Smeeth MBChB FRCGP FRCP MSc PhD FMedSci Professor of Clinical Epidemiology, London School of Hygiene & Tropical Medicine ([LSHTM](#)) & [MHRA](#), Non-Executive Director (Board)

Visiting Experts

Professor Andrew Pollard FRCPCH PhD FMedSci Chief Investigator of the Oxford ChAD vaccine

Professor of Paediatric Infection and Immunity, Director of Graduate Studies, Department of Paediatrics, Vice Master, St Cross College, University of Oxford & Member of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)

Professor Robin Shattock Lead Scientist for the Imperial saRNA vaccine programme

Professor Sheena McCormack Clinical Project Lead at MRC CTU at UCL

COVID-19 Vaccines Benefit Risk Expert Working Group

Remit

- To advise [CHM](#) on the quality, safety and efficacy of COVID-19 vaccines and on the balance of benefit and risks prior to authorisation.
- To coordinate safety evaluation with the Clinical Trials, Biologicals and Vaccines Expert Advisory Group.
- To report its conclusions and recommendations to the Commission on Human Medicines.
- To advise on the emerging evidence from all data sources on the risks and benefits of vaccine(s) during the course of any COVID-19 immunisation campaign in the UK. This includes measures to minimise risks, and optimise the benefit-risk balance for individual vaccines, such as any new precautions or restrictions on use.
- To advise on any communications to health professionals and the public.
- To advise on measures to monitor impact/effectiveness of any additional risk minimisation.

Chair

Professor Sir Munir Pirmohamed MB ChB (Hons) PhD FRCP FRCP (Edin) FBPhS, FFPM (Hon) FMedSci David Weatherall Chair of Medicine, University of Liverpool, NHS Chair of Pharmacogenetics, Director of the Wolfson Centre for Personalised Medicine, Director of the MRC Centre for Drug Safety Science

Members

Professor Judith Breuer MD FRCPPath FmedSci Professor of Virology, University College London (UCL), Division of Infection and Immunity, London

Professor Gordon Dougan FRS Department of Medicine, Cambridge Infectious Diseases, University of Cambridge

Professor Neil French MB ChB FRCP PhD Head Department of Clinical Infection Microbiology and Immunology, Chair of Infectious Diseases & Global Health, Hon Consultant Infectious Diseases, Royal Liverpool & Broadgreen University Hospitals Trust

Professor David Goldblatt MB ChB FRCPC FRCP PhD Professor of Vaccinology and Immunology, Consultant in Paediatric Immunology, NIHR Senior Investigator, Great Ormond Street Hospital & University College London

Ms Susan Hunneyball BSc Lay Member, Member of the Pharmacovigilance Expert Advisory Group (PEAG) and Advisory Board on the Registration of Homeopathic Products (ABRHP)

Professor Kimme Hyrich MD PhD FRCPC Professor of Epidemiology and Honorary Consultant in Rheumatology, Centre for Musculoskeletal Research, Faculty of Biology Medicine and Health, University of Manchester and Kellgren Centre for Rheumatology, Manchester University NHS Foundation Trust

Sir Michael Jacobs MA PhD MB BS FRCP FRCP Edin DTM&H Clinical Director of Infection, Royal Free London NHS Foundation Trust, Hon. Senior Lecturer, Liverpool School of Tropical Medicine & Member of the [CHM](#) Covid-19 Vaccine Expert Working Group

Professor Helen J Lachmann MA MB BChir MD FRCP FRCPPath Professor of Medicine & Honorary Consultant Nephrologist Clinical Director UCL Division of Medicine & Clinical Lead for National Amyloidosis Centre, University College London & Royal Free Hospital London NHS Foundation

Trust & Vice-chair of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)

Professor Paul J Lehner PhD FRCP FMedSci Professor of Immunology and Medicine, Wellcome Trust Principal Research Fellow Honorary Consultant Infectious Diseases, Cambridge Institute of Therapeutic Immunology and Infectious Disease (CITIID), Jeffrey Cheah Biomedical Centre Cambridge Biomedical Campus

Dr Siraj Misbah MBBS (Hons) MSc FRCP FRCPATH Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals & Member of the Commission on Human Medicines (CHM) & Chair of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)

Professor Shirley Price MSc, PhD, FBTS, FRSB, ERT, FHEA, FRSC, MBPharmacolSoc Emerita Professor of Toxicology, University of Surrey Visiting Professor of Toxicology, University of Hertfordshire

Dr Andrew Riordan MD FRCPCH DTM&H Consultant in Paediatric Infectious Diseases and Immunology, Honorary Clinical Lecturer, University of Liverpool, Alder Hey Children's NHS Foundation Trust, Liverpool

Professor Chris Robertson PhD MSc BSc Professor of Public Health Epidemiology, University of Strathclyde

Professor Tom Solomon FRCP PhD Chair, Neurological Science and Director, NIHR Health Protection Research Unit in Emerging and Zoonotic Infections, University of Liverpool, Hon Consultant Neurologist, Walton Centre NHS Foundation Trust

Dr Robin Thorpe BSc PhD FRCPATH Retired, Head, Division of Biotherapeutics, National Institute for Biological Standards and Control (NIBSC) & Member of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)

Mrs Madeleine Wang BA (Hons) Lay Member & Member of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)

Professor Christopher Weir BSc MSc PhD FRSS Cstat Professor of Medical Statistics & Clinical Trials, Edinburgh Clinical Trials Unit, Usher Institute, University of Edinburgh & Member of Commission on Human Medicines (CHM) & Member of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)

Invited Members of The Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG)

Professor B Kevin Park BSc, PhD, Hon FRCP, FMedSci, FBTS, HonFBPhS Professor of Pharmacology, Department of Pharmacology, University of Liverpool

Professor Marc Turner MBBS PhD MBA FRCP FRCPATH FHEA Professor of Cellular Therapy; Medical Director Scottish National Blood Transfusion Service (SNBTS)

Invited Members of The Chemistry, Pharmacy and Standards Expert Advisory Group (CPS EAG)

Professor Kevin M G Taylor BPharm PhD FRPharmS (Chair) Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

Mr V'lain G Fenton-May BPharm MIPharm FRPharmS Pharmaceutical Microbiologist

Mr Robert Lowe BPharm FRPharmS Practising Hospital Pharmacist, Specialist Pharmacy Services - East of England

Professor Yvonne Perrie BSc Hons MRPharmS FAPS FSB PhD Chair in Drug Delivery, Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow. Scotland

Professor Susannah E Walsh PhD BSc MBA Associate Head School of Pharmacy, Professor of Pharmaceutical Microbiology, Leicester School of Pharmacy, De Montfort University, Leicester

Observer

Professor Stuart Ralston MB ChB MD FRCP FMedSci FRSE FFPM (Hon) Professor of Rheumatology, University of Edinburgh, Western General Hospital, Edinburgh

Invited Experts (participation at specific meetings only)

Professor Ian J Douglas BSc MSc PhD Senior Lecturer in Pharmacoepidemiology, London School of Hygiene & Tropical Medicine & Member of the Pharmacovigilance Expert Advisory Group (PEAG)

Professor Paul-Henri Lambert MD Senior Adviser, Centre of Vaccinology, University of Geneva, Department of Pathology and Immunology, CMU

Professor Linda Sharples PhD Professor of Medical Statistics, London School of Hygiene & Tropical Medicine (LSHTM) and Faculty of Epidemiology and Population Health