OFFICIAL PROGRAM
NCIRS
Vaccine Safety Seminar
Active surveillance for adverse events following immunisation – new methods in vaccine pharmacovigilance

Wednesday 29 October 2014 | 8.30am - 5.00pm
Harbourview Hotel, 17 Blue Street, North Sydney

This seminar will bring together researchers, immunisation providers and public health staff interested in active surveillance for adverse events following immunisation (AEFI) and will share, and aim to improve upon, current methods of active and enhanced surveillance.

This meeting aims to strengthen collaborative efforts across state, territory and national systems to improve vaccine safety surveillance.

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NCIRS
NATIONAL CENTRE FOR IMMUNISATION RESEARCH & SURVEILLANCE

Australian Government
Department of Health
## PROGRAM

### SESSION 1: Active post-marketing surveillance of vaccine safety – why do we need it?

**Chair:** Dr Tony Hobbs – Therapeutic Goods Administration

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<td>What is active surveillance and how does this complement passive surveillance?</td>
<td>A/Prof Kristine Macartney NCIRS</td>
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<td>Overview of systems for active post-marketing surveillance in the USA</td>
<td>Dr Jennifer Nelson Group Health Research Institute, USA</td>
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<td>Why should we engage our patients in vaccine pharmacovigilance?</td>
<td>A/Prof Chris Blyth – Princess Margaret Hospital - WA</td>
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<td>Ms Alison Marcus – Consumer Health Forum</td>
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**Panel Discussion** – Tony Hobbs, Hazel Clothier + Session 1 speakers

### SESSION 2: Surveillance using active patient follow-up

**Chair:** A/Prof Chris Blyth – Princess Margaret Hospital WA

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<td>Ms Annette Regan Department of Health - WA</td>
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<td>GP-based automated vaccine safety surveillance: SMART VAX</td>
<td>Dr Alan Leeb General Practice - WA</td>
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<td>An RCT of parental-based reporting of AEFI: STARRS</td>
<td>A/Prof Mike Gold University of Adelaide - SA</td>
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<td>Vaxtracker: a web-based survey tool for vaccine safety</td>
<td>Mr Patrick Cashman HNE Public Health Unit - NSW</td>
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<td>Going national: AusVaxSafety 2014 and beyond</td>
<td>Dr Gulam Khandaker NCIRS</td>
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**Panel Discussion** – Tony Hobbs, Ian Peters (Datavation), Stephen Clarke (ChordWizard Systems) + Session 2 speakers
1.00 – 2.00pm Lunch

### SESSION 3: Surveillance for adverse events of specific interest

**CHAIR:** Dr Nicole Gilroy – St Vincents Hospital NSW

| Enhanced surveillance in school-based immunisation programs: HPV 2013 | Dr Bronwen Harvey  
Therapeutic Goods Administration |
| Hospital-based sentinel surveillance for AEFI – the PAEDS network | Dr Nick Wood  
NCIRS |
| Sentinel site surveillance for rare complex conditions and the power of international collaboration | Dr Nigel Crawford  
MCRI, SAEFVIC |
| Can automated data from Emergency Department data collections help to assess vaccine safety? | A/Prof Jim Buttery  
MCRI, SAEFVIC |

3.15 – 3.45pm Afternoon tea

### SESSION 4: Using large healthcare databases to assess vaccine safety

**CHAIR:** Dr Tom Snelling – Telethon Kids Institute WA

| Using large healthcare databases in the USA to assess vaccine safety | Dr Jennifer Nelson  
Group Health Research Institute, USA |
| GP encounter data to assess vaccine safety | Dr Rob Menzies  
NCIRS |
| Can data linkage of the ACIR be used for vaccine safety surveillance? | A/Prof Mike Gold  
University of Adelaide - SA |
| Communicating vaccine safety to the public | Dr Paul Effler  
Department of Health - WA |

PANEL DISCUSSION and Q&A – Session 4 speakers

CLOSE: Kristine Macartney
**Professor Chris Baggooley AO**

Professor Chris Baggooley is Chief Medical Officer for the Australian Government and is the principal medical adviser to the Minister and the Department of Health.

Prior to his appointment Professor Baggooley was the Chief Executive of the Australian Commission on Safety and Quality in Health Care. He was a former Chief Medical Officer and Executive Director with the South Australian Department of Health. His clinical career has been in emergency medicine.

**Dr Jennifer Clark Nelson**

Dr Jennifer Nelson is Director of Biostatistics and a Senior Investigator in the Biostatistics Unit at Group Health Research Institute (GHRI) and an Affiliate Associate Professor of Biostatistics at the University of Washington. She received her PhD from the Department of Biostatistics at the University of Washington in 1999. Dr Nelson’s research focuses on methods to assess drug and vaccine safety and effectiveness, and she has published over 50 studies in this area. She is particularly interested in addressing methodological challenges in post-licensure drug and vaccine safety studies that use large observational healthcare databases. Dr Nelson provides national leadership as the Methods Core Co-Lead and Senior Statistician for the Food and Drug Administration’s (FDA) Mini-Sentinel Initiative, a pilot project to facilitate development of an active surveillance system for monitoring the safety of all FDA-regulated medical products. She has also served as Methodology Committee Chair for the Centers for Disease Control and Prevention (CDC) sponsored Vaccine Safety Datalink (VSD) project, a national collaboration involving 10 managed care organisations that has monitored immunisation safety in the USA since 1990. In 2009, Dr Nelson earned the VSD’s Margarette Kolczak Award for outstanding contributions in biostatistics and epidemiology in the field of vaccine safety. She is also an invited member of the Vaccines Sub-Committee of the International Society for Clinical Biostatistics (ISCB), a group established to facilitate collaboration among statisticians working in vaccine research and to disseminate statistical methods for vaccine research worldwide.

**Dr Anthony (Tony) Hobbs**

Dr Anthony (Tony) Hobbs joined the Therapeutic Goods Administration (TGA) in February 2013 as the Principal Medical Adviser. Previously he was a general practitioner in rural NSW and former Chair of the Australian General Practice Network. Dr Hobbs has made a significant contribution to Australia’s health system as Chair of the External Reference Group that in 2008–09 developed Australia’s first national Primary Health Care Strategy. Dr Hobbs has had extensive experience on boards, committees and advisory councils, including National Health and Medical Research Council, university, cancer, diabetes and kidney health advisory groups.

Dr Hobbs has a First Class Honours Medical degree from the University of Sydney, and postgraduate qualifications in Gynaecology and Obstetrics, Child Health and Tropical Medicine and Hygiene from Australia and the United Kingdom. Dr Hobbs is also a graduate of the Australian Institute of Company Directors, and has been involved with the National Prescribing Service on its diagnostic evaluation advisory group. His wealth of experience and expertise adds significantly to the contribution of the TGA to Australia’s health system.
**Associate Professor Kristine Macartney**

Associate Professor Kristine Macartney is a paediatrician specialising in infectious diseases. She is a medical graduate of the University of New South Wales, and gained much of her experience in the United States where she worked at the Children's Hospital of Philadelphia. Her Doctorate of Medicine was on rotavirus infection, in particular the mucosal immune response to novel vaccine candidates. She was also a member of the Vaccine Education Center at the Children's Hospital of Philadelphia, and is interested in all aspects of vaccine preventable disease research.

Associate Professor Macartney has a clinical appointment at The Children's Hospital at Westmead as a Staff Specialist in Infectious Diseases and Microbiology and a conjoint academic appointment as Associate Professor in the Discipline of Paediatrics and Child Health of the University of Sydney.

**Associate Professor Chris Blyth**

Associate Professor Chris Blyth is an infectious diseases physician, clinical microbiologist and Associate Professor with University of Western Australia, Princess Margaret Hospital, PathWest and the Telethon Kids Institute. He has numerous interests including epidemiology, diagnosis, management and prevention of childhood infection with a particular focus on influenza, upper and lower respiratory tract infection, pneumonia, respiratory co-infection, emerging viral pathogens and vaccine safety. He is a sitting member of the Australian Technical Advisory Group on Immunisation.

**Ms Alison Marcus**

Ms Alison Marcus has been an active member of the Consumer Health Forum since 2003. She currently represents consumer interests on the National Immunisation Committee (DOH) and the Advisory Committee on the Safety of Medicines (TGA), and is involved in a number of community organisations. Alison is a registered nurse and has worked in metropolitan, regional and remote areas in a variety of specialties.

**Ms Hazel Clothier**

Ms Hazel Clothier is an epidemiologist with special interest in vaccine safety surveillance. Currently the Surveillance Manager with SAEFVIC Victoria, Hazel is also editor of the *Victorian Infectious Diseases Bulletin* and a senior lecturer at Melbourne University where she is the co-ordinator for the Infectious Disease Epidemiology unit.

Initially qualifying in Biomedical Science in 1989 and achieving her Fellowship in 1992, Hazel moved to the public health arena in 1994 as an advisor to the Ministry of Health in Vanuatu (1994–1997) followed by four years with the Pacific Regional Vector-Borne Diseases Project based in Fiji. Hazel completed a Master of Infectious Diseases from the London School of Hygiene and Tropical Medicine via distance learning in 2002 and attained a Master of Applied Epidemiology (Australian National University) in 2005 during which time she was an epidemiology registrar with the Communicable Diseases Unit at the Department of Health, Victoria, followed by two years at the Victorian Infectious Diseases Reference Laboratory before joining SAEFVIC.
Ms Annette Regan

Ms Annette Regan is a Project Officer for the Prevention and Control Program at the Communicable Disease Control Directorate, Western Australian Department of Health, where she coordinates surveillance systems for monitoring vaccine preventable diseases and adverse events following immunisation. For the past two years, she has administered the FASTMum program, a vaccine safety program for monitoring influenza vaccinations given during pregnancy, which has recently moved toward data capture using mobile phone technology. Prior to moving to Perth, she was an epidemiologist for the US Centers for Disease Control and Prevention in the Office on Smoking and Health. She received a Masters of Public Health in Epidemiology from the Rollins School of Public Health at Emory University and a Bachelor of Science in Psychology from the University of Florida. She is currently in her second year as a PhD Candidate with the School of Pathology and Laboratory Medicine at the University of Western Australia, where her doctoral research focuses on the effectiveness of maternal influenza vaccination in preventing influenza infection in young infants.

Dr Alan Leeb

Dr Alan Leeb is practice principal at the Illawarra Medical Centre (IMC) in Perth, Western Australia. IMC is a large privately owned multidisciplinary teaching practice with a strong focus on undergraduate and postgraduate training and research. Alan holds positions on a variety of boards and professional medical organisations. Alan is passionate about general practice and has special interests in paediatrics and immunisation as well as primary care research.

Associate Professor Mike Gold

Associate Professor Mike Gold is a Paediatric Allergist and Immunologist who holds a conjoint position in the Discipline of Paediatrics and is Head of Paediatric Allergy and Immunology at the Women’s and Children’s Health Network. He was appointed to the WHO Global Advisory Committee for Vaccine Safety in 2010 and has conducted WHO vaccine safety training courses internationally in multiple countries and has provided expert opinion to the WHO during investigations of vaccine safety concerns. He is a member of a number of expert committees concerned with vaccine safety including the Therapeutic Goods Administration Advisory Committee for the Safety of Vaccines.

He is principal investigator on an Australian Research Council grant which is investigating the feasibility and acceptability of cross-jurisdictional data linkage and an NHMRC Partnership Project investigating e-health for rapid safety surveillance.

Mr Patrick Cashman

Mr Patrick Cashman (RN, BHSc, MPH&TM, GCertAppMgt) has worked in Victoria, Tasmania, the Northern Territory and NSW in emergency, infectious diseases and remote health. Currently Patrick is the Immunisation Coordinator at Hunter New England LHD NSW. His operational and research interests include health worker education, Aboriginal immunisation and AEFI surveillance.
Dr Gulam Khandaker

Dr Gulam Khandaker is an NHMRC Early Career Fellow and Public Health Advanced Trainee Registrar. He is a physician researcher and has an academic appointment as Lecturer in the Sydney Medical School at the University of Sydney. He is dedicated to a joint career in public health and clinical research in diseases of clinical importance to Australasia (i.e. severe central nervous system infections). He has completed his internship and residency training in Queensland and basic physician training in pediatrics and child health at The Children’s Hospital at Westmead. During his clinical training, he has concurrently undertaken a highly successful PhD on the epidemiology, control and management of influenza in children through the University of Sydney.

Mr Ian Peters - Datavation

Mr Ian Peters is the developer of clinical data extraction tools used in general practice throughout Australia. Ian has been developing a wide range of extraction tools since 2005 and it is estimated that they have been installed in approximately 2000 practices over the years. The most well-known tool is the Canning Tool which was originally designed for divisions of general practice, now Medicare Locals, to collect data for their reporting requirements. The tool is now commonly used by practices for their own data analysis and can extract directly from five different clinical systems. Through his business, Datavation, Ian develops a range of customised extraction tools for state health departments, government-funded organisations, universities, practices and private companies. The most interesting project that Ian has ever worked on is SmartVax – an extraction tool that provides near real-time monitoring of vaccine safety using SMS technology.

Mr Stephen Clarke - ChordWizard Systems

Mr Stephen Clarke (BE Elec, Hons) is a freelance software architect with 30 years experience in a wide range of platforms and languages. His primary focus has been the design and development of enterprise management and web systems, and he has also produced his own line of music software under the ChordWizard brand. Stephen has been involved with public health surveillance since 2009, when he joined Dr Craig Dalton on the Flutracking team. Over the years, he has supported, extended and ultimately rebuilt the Flutracking system on an improved web platform.

In 2011, Stephen was commissioned by Hunter New England Health to design and build the prototype Vaxtracker system for monitoring AEFI, and has worked with Patrick Cashman and Craig Dalton over several pilot seasons, as it has grown into a multi-mission facility operating under the umbrella of NCIRS and AusVaxSafety. Stephen has attended, under the Flutracking banner, both sessions of the International Workshop on Participatory Surveillance (IWOPS) organised by the Skoll Global Threats Fund and held in San Francisco and Amsterdam. He was also involved in the Epihack workshop in Phnom Penh, which had a particular focus on using technology to improve public health outcomes in developing countries.

Stephen is currently designing and building the web system which will manage the STARSS study, to be conducted by Dr Michael Gold and Gabriella Lincoln at the University of Adelaide.
Dr Nicole Gilroy
Dr Nicole Gilroy is a consultant physician in infectious diseases for the Bone Marrow Transplant Network, NSW, and Staff Specialist at St Vincent’s Hospital Sydney. She was a member of the Australian Technical Advisory Group on Immunisation (ATAGI) from 2005 to 2014 and is the current chair of the Advisory Committee on the Safety of Vaccines (ACSOV). She has expertise in the fields of adult infectious diseases, infection control and prevention, epidemiology and public health.

Dr Bronwen Harvey
Dr Bronwen Harvey is the Director of the Signal Investigation (Medicines) Unit within the Office of Product Review at the Therapeutic Goods Administration. The Unit is responsible for monitoring the safety of all medicines and vaccines on the market in Australia.

Bronwen has worked in the Australian Government Department of Health since 1992, across a variety of policy and program areas, including the Immunisation Branch. She assisted Professor Horvath in undertaking the review of the national response to Fluvax adverse events in young children in 2010.

Dr Nick Wood
Dr Nick Wood is a staff specialist general paediatrician and senior lecturer in the Discipline of Paediatrics and Child Health at the University of Sydney. He is involved in the Immunisation Adverse Events Clinic and Refugee Clinic at The Children’s Hospital at Westmead. He is interested in maternal and neonatal immunisation, as well as immunisation in Indigenous communities and developing countries.

Dr Nigel Crawford
Dr Nigel Crawford is a consultant paediatrician and Medical Head of Immunisation Services at the Royal Children’s Hospital and the Deputy Director of SAEFVIC (an immunisation research and vaccine safety group) based at the Murdoch Childrens Research Institute in Melbourne. His research interests include special risk groups and adverse events following immunisation. Nigel was appointed to the Australian Technical and Advisory Group on Immunisation in 2014.

Associate Professor Jim Buttery
Associate Professor Jim Buttery is a paediatric infectious diseases physician and vaccinologist who trained in Melbourne and Oxford, UK. He has been involved in the development of multiple vaccine candidates, including meningococcal and pneumococcal glycoconjugate vaccines and Japanese encephalitis vaccines, and is an investigator in the development program of the RV3 candidate rotavirus vaccine in trials in New Zealand and Indonesia. He has worked as a consultant for WHO in vaccine safety and is a temporary advisor for the global Vaccine Safety Initiative and an investigator in the Global Vaccine Safety Multi-Country Collaborative Project.

He is head of Infectious Diseases and Director of Research at Monash Children’s Hospital and Head of Monash Immunisation, Monash Medical Centre, Melbourne. He leads SAEFVIC, the Victorian immunisation safety service, and is an Associate Professor in the Department of Paediatrics, Monash University. He is the president of the World Society of Pediatric Infectious Diseases, and serves as a member of the Science Board of the Brighton Collaboration, the Australian Pharmaceutical Benefits Advisory Committee and the Advisory Committee on the Safety of Vaccines.
Dr Tom Snelling

Dr Tom Snelling is a paediatric infectious diseases physician at the Princess Margaret Hospital for Children in Perth and recipient of the first NHMRC Frank Fenner Fellowship. He is also a Fiona Stanley Investigator and Scientific Director of the newly formed Wesfarmers Centre of Vaccines and Infectious Diseases at the Telethon Kids Institute. Tom’s clinical and research interests are in infectious diseases and Aboriginal child health. His research is largely driven toward addressing specific vaccine policy questions. His work to date has focused largely on rotavirus and pertussis vaccines, demonstrating and quantifying how vaccine protection against both of these diseases wanes as children get older. His current projects are assessing pneumococcal vaccine effectiveness and impact, vaccine safety surveillance, treatments for diarrhoea, antimicrobial stewardship, impacts of diarrhoeal vaccination and RSV epidemiology. In addition to his clinical and research work, Tom sits on a number of representative and expert advisory bodies.

Dr Rob Menzies

Dr Rob Menzies worked in communicable disease surveillance and epidemiology in Australia and developing countries for a decade before joining NCIRS in 2002. His PhD was conducted at NCIRS, on the epidemiologic analysis of routinely collected data on Aboriginal and Torres Strait Islander people. He has a conjoint Senior Lecturer appointment at the Sydney Medical School, University of Sydney.

Dr Paul Effler

Dr Paul Effler received a Doctorate in Medicine from the University of California and a Master of Public Health from the University of Hawaii. Upon completing a residency in Public Health Medicine, Dr Effler served as an Officer in the Epidemic Intelligence Service at the US Centers for Disease Control. He subsequently worked as a consultant to the United Nations High Commissioner for Refugees in Africa and the World Health Organization. In 1994 he became the State Epidemiologist for Hawaii, where he directed the public health response to SARS, dengue fever, measles and influenza and oversaw Hawaii’s immunisation program. In 2008 Dr Effler moved to Perth where he works in immunisations and communicable disease control. He is an adjunct Professor at UWA and an Associate Editor for Emerging Infectious Diseases at the CDC.