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International Alliance for Biological Standardization

The Role of Real-World Evidence for Regulatory and Public Health Decision Making for Accelerated Vaccine Deployment

September 19 – 20, 2023

ParkInn Hotel

LEUVEN – BELGIUM

HYBRID MEETING

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P95

TURNING DATA INTO EVIDENCE

About the Conference

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Real-world evidence for monitoring the safety and benefits of vaccination has an essential role to play in the accelerated development and deployment of vaccines. Recently, the COVID-19 pandemic showed the necessity and feasibility of having new vaccines rapidly available. Despite the tremendous success of having several COVID-19 vaccines authorized less than 12 months after the declaration of the COVID-19 global pandemic, many challenges have been faced in both high and low-and-middle income countries. Capitalizing on the massive efforts spent by all takeholders, it is timely to learn important lessons for the future on how to best use real-world evidence for regulatory and public health decision-making on vaccines and vaccination programs.

This hybrid meeting will bring together renowned vaccine experts from national and international public health authorities, regulatory bodies, industry, academia, and research organizations for developing recommendations on the best use of real-world evidence for vaccine decision making and a roadmap to further strengthen its use. The meeting brings an exciting mix of information sharing and discussion sessions among all key stakeholders from vaccine development till deployment.

Scientific and Organizing Committee

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Nick Andrews, UKHSA, United Kingdom

Steve Black, GVDN, USA

Kaat Bollaerts, P95, Belgium

Madinina Cox, IABS secretariat, France

Hector Izurieta, FDA, USA

Pieter Neels, IABS, Belgium

Jeffrey Roberts, Merck, USA

Bob Small, CEPI, USA

Julia Stowe, UKHSA, United Kingdom

Miriam Sturkenboom, UMC Utrecht, Netherlands

Joris Vandeputte, IABS Past President, Belgium

Fran Van Heuverswyn, Flanders Vaccine, Belgium

Melinda Wharton, CDC, USA

Scientific Program

Tuesday 19 of September, 2023

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8:30	Coffee and Registration
9:15	Welcome - **Joris Vandeputte, IABS Past President**
9:25	Bob Small Memorial - **Gabrielle Breugelmans, CEPI**
9:35	Objectives of the meeting - **Thomas Verstraeten, P95**

SESSION 1: The role of RWE for accelerating vaccine deployment

Chairperson: Thomas Verstraeten, P95

9:40	Key note duo presentation: Accelerated vaccine development in pandemic situations: what is needed? Link to Ebola outbreak in West Africa, 2014- 2016? **Helen Rees, Wits RHI and Jakob Cramer, CEPI**
10:10	PCV20 and RSV in older adults: similarities and differences for RWE - **Brad Gessner, Pfizer**

SESSION 2: Emergency Use Authorization of COVID-19 vaccines: regulatory and public health perspectives and actions

Chairperson: Liz Miller, LSHTM

10:25	EUA of COVID-19 vaccines: role of RWE and the EU Vaccine Monitoring Platform to evaluate safety and effectiveness - **Hector S Izurieta, FDA**
10:40	Use of RWE for COVID-19 regulatory decision making, the Nordic experience **Richard Ljung, Swedish Medical Products Agency**
10:55	Coffee Break
11:25	COVID-19 vaccines: role of RWE for public health decision making **Tom Shimabukuro, CDC**
11:40	**BREAK OUT #1*:** Which successful and not-so-successful decisions were based on RWE in pandemic situations? What went well and not so well, and why? **Liz Miller, London School of Hygiene & Tropical Medicine (moderator), all**
12:40	Lunch

Scientific Program

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SESSION 3: Experiences with using RWE for regulatory and public health decision-making on COVID-19 vaccines

Chairperson: Hector S. Izurieta, FDA

14:00	RWE use for COVID-19 public health decision-making in the UK: experiences, lessons learned, remaining challenges - **Nick Andrews, UKHSA**
14:15	RWE use for COVID-19 regulatory decision-making in the UK: experiences, lessons learned, remaining challenges - **Katherine Donegan, MHRA**
14:30	VAC4EU: experiences, lessons learned, remaining challenges **Miriam Sturkenboom, UMC Utrecht**
14:45	COVIDRIVE: experiences, lessons learned, remaining challenges **Kaat Bollaerts, P95**
15:00	Coffee Break
15:30	Example of use of RWE that supported decision-making (VE against symptomatic infection, duration, mix and match, booster) **Sylvia Taylor, AstraZeneca**
15:45	Global Vaccine Data Network: experience, lessons learned, remaining challenges - **Steve Black, GVDN**
16:00	ALIVE network: experience, lessons learned, remaining challenges **Clare Cutland, Wits RHI**

SESSION 4: Improving the use of RWE for regulatory and public health decision-making (part 1)

Chairperson: Steve Black, GVDN

16:15	**BREAK OUT #2*:** What is required and what are the main barriers experienced for a successful use of RWE for regulatory and public health decision making? - **Liz Miller, London School of Hygiene & Tropical Medicine (moderator), all**
17:15	End of day 1
19:30	Dinner

Scientific Program

Wednesday 20 of September, 2023

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SESSION 5: Improving the use of RWE for regulatory and public health decision-making (part 2)

Chairperson: Nick Andrews, UKHSA

9:00	The BeCOME project and its RWE roadmap - **Philip Bryan, GSK**
9:20	Brighton Collaboration's role in establishing a RWE infrastructure for vaccine safety during early deployment - **Bob Chen, BC**
9:35	Feedback from DAY 1, Introduction to break-outs - **Thomas Verstraeten, P95**
9:40	**BREAK OUT #3*:** How to overcome main "barrier # 1"** - **Liz Miller, London School of Hygiene & Tropical Medicine (moderator), all**
10:40	Coffee Break
11:10	**BREAK OUT #4*:** How to overcome main "barrier # 2"** - **Liz Miller, London School of Hygiene & Tropical Medicine (moderator), all**
12:10	Wrap up of the meeting, and next steps - **Liz Miller, London School of Hygiene & Tropical Medicine**
12:25	Lunch

SESSION 6: Experiences using RWE for health economics and public health decision- making on non-COVID-19 vaccination (by Flanders Vaccine)

Chairperson: Kaat Bollaerts, P95

14:00	Welcome by **Fran Van Heuverswyn, Flanders Vaccine**
14:05	Exploring the Cost-Effectiveness of Respiratory Syncytial Virus (RSV) Preventive Interventions in children with Real-World Evidence (IMI-RESCEU project) **Xiao Li, Health economist, University of Antwerp, Belgium**

Scientific Program

Wednesday 20 of September, 2023

SESSION 6: Experiences using RWE for health economics and public health decision- making on non-COVID-19 vaccination (by Flanders Vaccine)

Chairperson: Kaat Bollaerts, P95

14:30	Public Health Impact and Return on Investment of Belgium's Pediatric Immunization Program - **Olivier Ethgen, Professor Health Economics, Université de Namur & André Bento, Associate Director, HEOR Manager at MSD**
14:55	PERCH (PartnERship to Contrast HPV) project - **Hélène De Pauw, Sciensano**
15:15	Coffee Break
15:45	Health information for policy & decision-making on vaccination - **Laura Cornelissen, Sciensano**
16:15	Improving quality of evidence for decision making through innovative design and collaborative studies leveraging RWE platforms - **Laurence Pagnon, Sanofi**
16:40	Closing – **Joris Vandeputte, IABS Past President**

Upcoming IABS Conferences and Workshops

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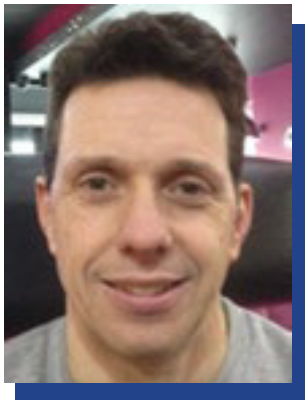
2023

9th Annual IABS Statistics Workshop

Applying Statistics and Data Science to Evolving Technical and Regulatory Paradigms

November 7-9, 2022

Biosketch



Nick Andrews

Head of vaccines analysis
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Prof Nick Andrews is Head of Vaccines Analysis within the Immunisation Department of the UK Health Security Agency. In this role he has worked extensively on post licensure real world vaccine safety, impact and effectiveness assessment, clinical trials and correlates of protection. He is currently part of the Global Vaccine Datanet, works on European influenza vaccine effectiveness projects with the IMove group, and was a member of the WHO Advisory Committee on Vaccine Safety (GACVS) from 2012-2018. He is on the WHO Ebola vaccine sub-committee and the WHO malaria vaccine advisory group. He is a project lead on a research collaboration on using electronic health records for vaccine assessment with the London School of Hygiene and Tropical Medicine (LSHTM). During the COVID-19 pandemic he has worked on sero-epidemiology, risk factors, excess mortality, and has published multiple studies on vaccine effectiveness and safety. He regularly provides evidence on COVID-19 vaccine effectiveness to the Joint Committee on Vaccination and Immunisation. He lectures at the LSHTM, New York University in London and on vaccine courses internationally. He has over 400 publications with more than half of these in the vaccine field.

Abstract

Nick Andrews

RWE use for COVID-19 public health decision-making in the UK: experiences, lessons learned, remaining challenges.

Prof. Nick Andrews, UK Health Security Agency

INTRODUCTION - COVID-19 vaccines were rolled out in the UK from Dec 8th 2020.

CHALLENGES - The immediate questions related to safety, in particular anaphylaxis, and to the optimal use of the vaccines in terms of the effectiveness of the first dose and whether the interval between doses could be extended. Rapid assessment of real-world data was required to complement clinical trial data.

APPROACH - Rapid assessment was achieved using linked data on covid testing and vaccine registry data. The fastest method used the test-negative case-control design, with later assessments of effectiveness done using cohort studies. Real world data were also used to assess population immunity and vaccine immunogenicity and to identify those at highest risk of severe COVID-19.
Results by manufacturer using different severity end points and against different strains were presented regularly to JCVI who advised and continue to advice on the vaccine strategy. A UK wide working group was set up to evaluate UK and international studies on effectiveness and come to a consensus. On the safety side UKHSA worked with the MHRA and University research groups to evaluate safety signals and help with risk benefit assessment, such as the risk of VITT (Vaccine-induced thrombocytopenia and thrombosis). Results were presented to JCVI and the vaccine benefit-risk expert working group run by the MHRA.

CONCLUSIONS - We have learnt that having rapidly available linkable data along with appropriate statistical methods for analysis is hugely beneficial for decision making. Expertise to critique and understand limitations of methods and communicate these clearly is also needed. Challenges remain to continue to develop and improve these data sources and to retain/improve access. Also, to further understand the best ways to quantify and minimize bias. Designing vaccine roll out in ways that make evaluation less likely to be biased is attractive but often limited by practical considerations.

Biosketch

André Bento

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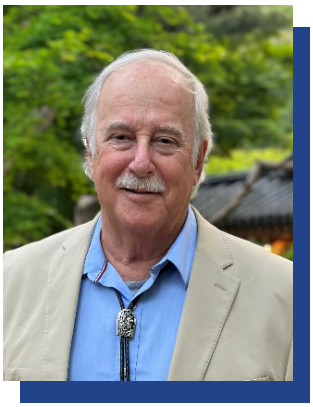
André Bento Abreu is an Associate Director at MSD Belgium; main activities include generation of economical evidence for Health Technology Assessment and research on Value Demonstration and Affordability.

Biosketch



Steve Black

Dr. Steven Black is a pediatric infectious disease specialist who received degrees in Biology and Chemistry from the University of California Santa Barbara and an MD degree from the University of California San Diego. He completed a fellowship in pediatric infectious diseases at the University of California San Francisco. He has spent more than 30 years conducting clinical trials and safety studies of vaccines including being the principal investigator in five pivotal licensure trials and six phase four post marketing trials. He has also conducted numerous phase 1-2 clinical trials. He is co-Director of the 25 country Global Vaccine Data network currently engaged in the safety evaluation of COVID-19 and other vaccines.

He is work package lead for DSMB activities for the CEPI funded SPEAC project supporting the assessment of vaccine safety in CEPI funded clinical trials. He is currently Emeritus Professor of Pediatrics at the University of Cincinnati Children's Hospital in Ohio USA and Honorary Professor of Pediatrics at the University of Auckland in New Zealand. He is editor in chief of the Pediatric Infectious Disease Journal.

Abstract

Steve Black

Global Vaccine Data Network: experience, lessons learned, remaining

Steven Black, Helen Petousis-Harris, Jim Buttery
Co-Directors, GVDN

BACKGROUND - Following the initial detection of a possible relationship between receipt of ASO3 adjuvanted 2009 influenza vaccine and narcolepsy in Europe, multiple studies were conducted with different protocols yielding widely disparate results – some with a 16 fold increased risk and others with no increased risk. To try and address the need for globally coordinated studies with harmonized protocols, the Global Vaccine Data Network was established in 2019.

CURRENT STATUS - In 2021 the US CDC funded the GVDN GCoVS project to evaluate the safety of COVID-19 vaccines and the network has grown to include more than 30 countries. Since that time, harmonized protocols have been developed to develop background rates, observed versus expected ratios, and to conduct association studies for Guillain-Barré Syndrome, myo-/peri-carditis, VITT, VMED and the safety of maternal immunization. The first two studies are complete whereas data collection is ongoing for the association studies.

LESSONS LEARNED - The GVDN GCoVS study was funded one year after the start of the COVID pandemic. Without existing infrastructure, it was very time consuming to establish relationships, build trust and develop the protocols. While most protocols contemplated hands on medical record review, this has been difficult to achieve in a timely manner. Inclusion of low-income countries has required developing a separate data system.

REMAINING CHALLENGES - While the GVDN is successfully conducting investigator led global collaborative studies, the timelines for each project have been long. Work is in progress to develop a rapid response protocol to address new safety questions urgently. As always, availability of sustainable funding is an ongoing challenge.

Biosketch

Gabrielle Breugelmans

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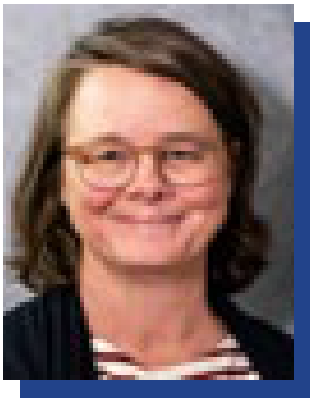
Dr Gabrielle Breugelmans is the Director of Epidemiology and Data Science at the Coalition for Epidemic Preparedness Innovations (CEPI). The Mission of the Epidemiology and Data Science department is to support CEPI, its partners, and stakeholders by bridging key epidemiological knowledge gaps for vaccine development and preparedness. Projects implemented by the department include amongst others the Enable Lassa fever programme. a large prospective cohort study in West Africa; development of a methodology to prioritize emerging pathogens for vaccine development; Covid-19 vaccine effectiveness studies in low-resource settings, and several modeling projects to assess vaccine impact and stockpile needs of CEPI's priority pathogens for routine and/or emergency use.

Dr. Breugelmans is an infectious disease epidemiologist with large expertise in global health, poverty-related diseases, access to medicines, and vaccinology in low-resource settings. She holds a Ph.D. and MPH in Epidemiology from the Johns Hopkins Bloomberg School of Public Health in the U.S. and a Master of Science degree in Health Sciences from the University of Maastricht in the Netherlands. Her research interests include epidemiological study designs, pharmacovigilance, pharmacoepidemiology, and epidemiological/ implementation issues related to the introduction of and access to new and improved medical interventions in low-resource settings.

Biosketch



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Biosketch

Robert Chen

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Dr. Chen has been active in research of vaccines and vaccine-preventable diseases for over 35 years, mostly at the US Centers for Disease Control and Prevention (CDC). He played key roles in modernizing the vaccine safety infrastructure in the U.S. and elsewhere. He has authored or coauthored over 300 publications. Dr. Chen is currently the Scientific Director of the Brighton Collaboration. He also Leads the Coalition of Epidemic Preparedness Innovation (CEPI)-funded Safety Platform for Emergency vACcines (SPEAC) Project, the US CDC-funded CARESAFE Project, and co-leads the COVAX Vaccine Safety Working Group.

Abstract

Robert Chen

Brighton Collaboration's role in establishing a real world evidence (RWE) infrastructure for vaccine safety during early deployment.

Chen RT, Black S, Dekker C, Law B, Gurwith M, Nordenberg D, Munoz F, Chaudhary M, Stergachis A, Huang WT, Sturkenboom M, Chandler R

INTRODUCTION - The Brighton Collaboration (BC) was officially established in 2000 with the goal to advance the science of vaccine safety, focusing initially on developing standardized case definitions (CD) to harmonize safety assessments. Since then, the import of vaccine safety for vaccine confidence has continued to grow, especially in the context of a) progress towards elimination of many target vaccine-preventable diseases (VPD) through high vaccine coverage, and b) plans to develop new vaccines vs. emerging "Disease X" pathogens in 100 days ("100-Day Mission").

CHALLENGES - Historically, vaccine safety assessments within pre-approval clinical trials tended to be separate from post-approval RWE. A "life cycle" approach integrating both pre- and post-approval processes while ideal, was more an aspiration than a reality. Furthermore, doing so in low- and middle- (as well as high income countries adds another layer of difficulty.

PROPOSED APPROACH - The Coalition for Epidemic Preparedness and Innovation (CEPI) funded BC's Safety Platform for Emergency vACcines (SPEAC) project in May 2019. Based on the lessons learned from the COVID-19 pandemic, SPEAC (as SPEAC 2.0) was renewed and expanded in November 2022. Building upon its core of Adverse Events of Special Interest (AESI) CDs, the SPEAC 2.0 project aims to implement the use of standardized safety outcomes throughout the vaccine lifecycle, to ensure both the generation and interpretation of robust evidence of safety for CEPI 2.0's "100-day mission". For each CEPI-funded developer, SPEAC activities start during the pre-approval process (e.g., identify potential AESI for target pathogen and platform technology, develop standard BC CD if needed, identify background rates for AESIs, assign a meta-Data Safety Monitoring Board liaison member, complete vaccine profile template). Using this foundation, SPEAC continues through preparation for post-approval RWE active surveillance (e.g., mobile app for Cohort Event Monitoring, pregnancy exposure registry). Each Work Package is also planning "Living Labs" to Quality Assure and continuously improve their respective products for eventual use by the larger vaccine safety community. A digital transformation of BC CDs seeks to facilitate their greater use in existing processes and infrastructures used to perform vaccine safety surveillance.

CONCLUSIONS - BC and CEPI are using SPEAC to establish a "life cycle" approach to vaccine safety, including RWE infrastructure during early deployment.

Biosketch

Laura Cornelissen

Scientific Expert and team leader for vaccine-preventable diseases
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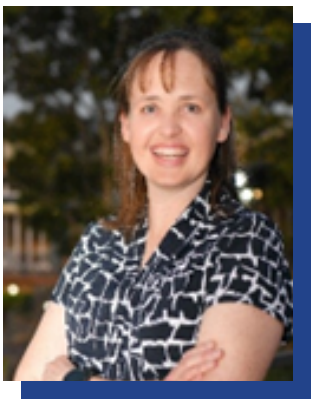
Dr. Laura Cornelissen is a medical doctor with a specialist degree in Obstetrics & Gynecology (KU Leuven) and an MSc in International Health (LSHTM). Since 2019, she is working at the Belgian Public Health Institute, Sciensano, at the department of epidemiology of infectious diseases, where she now leads the team of vaccine-preventable diseases.

As co-lead of the Belgian Risk Assessment Group and member of the Belgian NITAG, Dr. Cornelissen has first-hand experience with the challenges of advising policy makers in uncertain times. She acts as Belgian National Focal Point for vaccine-preventable diseases for ECDC and as such is also a member of the newly founded European Immunization and Vaccine Monitoring Board and the representative of Belgium in the EU-NITAG collaboration. As the scientific secretariat of the Belgian Elimination Committee for Measles & Rubella, she has a particular interest in these two diseases, but is strongly convinced of the importance of a holistic approach to vaccination programs.

Biosketch



Clare Cutland

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Dr Clare Cutland is the Scientific Coordinator of the Wits African Leadership in Vaccinology Expertise (Wits-Alive) consortium (Since Nov 2018). Previously, she spent 18 years as a clinical researcher in vaccinology at the Respiratory and Meningeal Pathogens Research Unit (RMPRU, now Wits-VIDA), at Chris Hani Baragwanath Academic Hospital (CHBAH), Soweto, South Africa.

She was an investigator on numerous phase I, II and III paediatric, maternal and COVID-19 clinical vaccine trials, and was the clinical lead for several large grant-funded neonatal sepsis prevention studies, maternal-neonatal sepsis surveillance studies and maternal immunization trials (Influenza, GBS, RSV). She was a member and lead of several GAIA Brighton collaboration definition working groups (2014-2020), and was elected as a member of the scientific board of the Brighton collaboration in 2018.

She coordinates a biennial short course in vaccinology (Afro-ADVAC) and a Masters of Science (Med) in the field of vaccinology at The University of the Witwatersrand, and is the chair of the International Collaboration on Advanced Vaccinology Training (ICAVT).

She is coordinating the Gavi-funded African COVID-19 Vaccine Safety Surveillance (ACVaSS) project in 8 African countries. She is author or co-author on over 120 peer-reviewed journal articles.

Abstract

Clare Cutland

Active COVID-19 safety surveillance in Africa: update & lessons learnt

Clare Cutland, Scientific coordinator
African Leadership in Vaccinology Expertise, University of the Witwatersrand (Wits-Alive)

BACKGROUND - Pharmacovigilance (PV) systems in low and middle income countries (LMICs) are limited due to resource and expertise constraints. The disparities between PV systems globally were highlighted during the COVID-19 pandemic. Two demonstration projects were established in Africa to estimate the risk of predefined adverse events of special interest (AESIs) with acute onset and short period of increased risk following immunization of the COVID-19 vaccine using a self-controlled risk interval (SCRI) study design. Predefined AESIs included generalized convulsions, myocarditis, pericarditis, anaphylaxis, thrombocytopenia, thrombocytopenia syndrome (TTS), Guillain Barré syndrome (GBS), Miller Fisher Syndrome (MFS), Acute Disseminated encephalomyelitis (ADEM), encephalitis, and myelitis.

METHODS - Hospital-based sentinel active COVID-19 vaccine safety surveillance studies were established at facilities across nine African countries: (i) Active COVID-19 vaccine safety surveillance (ACVaSS) in eight COVAX-92 Advanced Market Commitment (AMC-92) eligible countries including Ethiopia, Ghana, Kenya, Mali, Malawi, Mozambique, Nigeria and Eswatini and (ii) the South African COVID-19 vaccine safety surveillance study. Patients presenting to hospital with an acute illness suggestive of a predefined AESIs were screened for study participation, and eligible, consenting patients were enrolled between October 2021 (SA)/ April 2022 (ACVaSS) and March 2023. Data were collected from medical records, COVID-19 vaccination cards and registers, and from the patient and entered into a study-specific, centralised REDCap database, and were analysed using R software version 4.3.1. Brighton Collaboration case definitions were used. The ACVaSS study was funded by Gavi, The Vaccine initiative, and the South African study was funded by the Global Vaccine Data Network (GVDN). GVDN provided technical support to both studies.

RESULTS - A total of 60 511 patients were screened on hospital admission, of whom 12 756 were enrolled into the studies. Challenges encountered included delays in obtaining ethics approvals and establishing sites; limited laboratory- and imaging capacity and limited access to medical- and vaccination records.

CONCLUSIONS - These studies have demonstrated that establishment of sentinel active surveillance sites is feasible in LMICs, despite challenges encountered.

Biosketch

Hélène de Pauw

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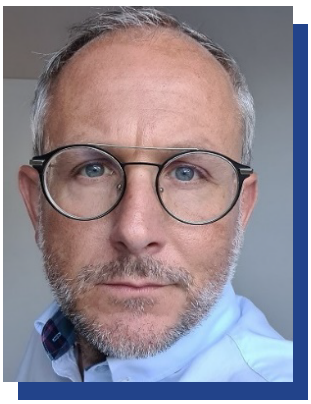
Hélène De Pauw is a Research Scientist at Sciensano.

Hélène graduated with a Bachelor of Science in Nursing (HENALLUX, 2014) and a master's degree in Science of Public Health (UCLouvain, 2017). She works for Sciensano since October 2017. She first integrated the Unit of Healthcare-Associated Infections and Antimicrobial Resistance (NSIH). Since 2019, she works in the Unit Cancer Epidemiology, which is part of the Belgian Cancer Centre. Her research activities focus on cervical cancer screening and HPV vaccination. She is currently working on the PERCH (Partnership to Contrast HPV) project. The overall aim of this project is to contribute to the implementation of the European Plan to beat cancer, which seeks to support Member States' actions to strengthen routine HPV vaccination in order to eliminate cervical cancer and other cancers caused by HPV over the next decade.

Hélène is Board member of the CCR (Centre Communautaire de Référence pour le dépistage des cancers) which is an accredited non-profit organisation responsible for managing breast and colorectal cancer screening programmes in Wallonia. She also represents Sciensano in Belgian association, such as BRUPREV, which is an association in charge of organising cancer screening and prevention in the Brussels Region. Hélène is also investigating, through various projects, the use of self-sampling in an organised cervical cancer screening programme.

Biosketch



Olivier Ethgen

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Olivier is Associate Professor of Health Economics at the Department of Public Health Sciences, Faculty of Medicine, University of Liège in Belgium. He is also an invited lecturer at the Department of Pharmacy and the Department of Biomedical Sciences, Faculty of Medicine, University of Namur in Belgium. He lectures in health economics (theory & applied modeling), decision sciences and pharmacoepidemiology. Olivier holds a PhD in Public Health Sciences from the University de Liège and an MSc in Mathematical Economics from the University of Paris I - Panthéon Sorbonne. His research interests include financial modeling of patients and market access strategies and population-based modeling. His experience spans all types of healthcare technologies including drugs, biologics, vaccines, devices, and diagnostics.

Biosketch

Xiao Li

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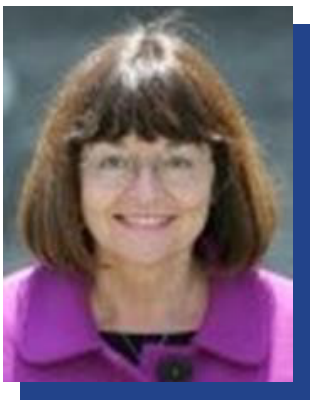
Dr. Xiao Li is a health economist at the Centre for Health Economics Research and Modelling Infectious Diseases, Vaccine and Infectious Disease Institute, University of Antwerp, Antwerp, Belgium. She is specialised in modeling and cost-effectiveness analyses for infectious diseases. She has more than 14 years of experience in conducting multi-country health economic evaluations on several vaccines, including respiratory syncytial virus, hepatitis B, human papillomavirus, rotavirus, pertussis, varicella and influenza. She is also a member of RESCEU (REspiratory Syncytial virus Consortium in Europe) and PROMISE (Preparing for RSV immunisation and surveillance in Europe).

Biosketch



Elizabeth Miller

Elizabeth (Liz) Miller BSc, MBBS, FRCPath, FMedSci
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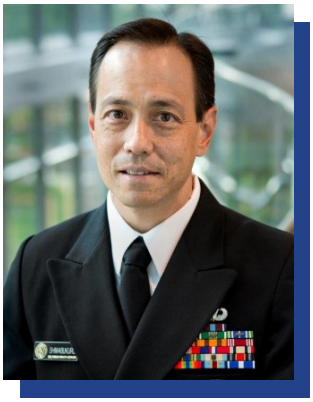
Professor Elizabeth Miller is an infectious disease epidemiologist who has worked on vaccines and immunisation programmes for over 40 years. She was the former Head of Immunisation at Public Health England and is now a professor in the department of Infectious Disease Epidemiology at the London School of Hygiene and a visiting professor at the School of Public Health a Tel Aviv University. She has considerable experience in evaluating vaccine safety and effectiveness and served as a member of the WHO Strategic Advisory Group of Experts (SAGE) on Immunisation and was a founder member of the WHO Global Advisory Committee on Vaccine Safety (GACVS). In response to the SARS-CoV-2 pandemic she lead the PHE (now UKHSA) studies of household transmission of the virus and the effect of vaccination in the household setting and is currently working with UKHSA colleagues on various studies of COVID-19 vaccine safety.

She is also working for the WHO in assessing COVID-19 vaccines that are candidates for inclusion in the WHO efficacy trials (SOLIDARITY) that are being conducted in low and middle income countries, and candidate vaccines for evaluation in viral haemorrhagic outbreaks.

Biosketch



Tom Shimabukuro

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Dr. Tom Shimabukuro is the director of the Immunization Safety Office at the U.S. Centers for Disease Control and Prevention (CDC). He has been with the Immunization Safety Office since 2010 where he has served in a variety of positions to include senior medical officer, Vaccine Adverse Event Reporting System (VAERS) team lead, acting Vaccine Safety Datalink (VSD) team lead, vaccine safety team lead in the CDC COVID-19 Vaccine Task Force, deputy director, and director.

Abstract

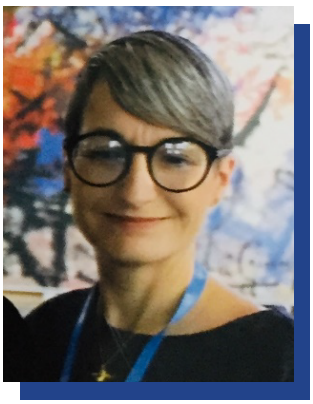
Tom Shimabukuro

Real-world vaccine safety evidence and public health decision making in the United States during the COVID-19 vaccination program

Dr. Tom Shimabukuro, Director, Immunization Safety Office U.S. Centers for Disease Control and Prevention (CDC)

The U.S. Centers for Disease Control and Prevention (CDC) uses multiple, complementary public health surveillance systems and programs to monitor the safety of vaccines authorized or licensed for use in the United States. COVID-19 vaccines were administered under the most intensive vaccine safety monitoring effort in U.S. history. During the pandemic vaccination program, >676 million COVID-19 vaccine doses were administered in United States and 81.4% of the population received at least one dose of a COVID-19 vaccine. Two examples highlight the effectiveness of CDC's vaccine safety monitoring programs in generating actionable real-world evidence, myocarditis following the Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines and thrombosis with thrombocytopenia syndrome (TTS) following the Janssen adenoviral-vectored COVID-19 vaccine. In these two examples, CDC vaccine safety monitoring systems detected and assessed safety signals and quantified the risk of these adverse events following vaccination. This real-world evidence contributed to regulatory and public health action. Warnings were added to regulatory documents, clinical considerations were updated, and vaccine recommendations were issued, including an eventual preferential recommendation for the use of mRNA COVID-19 vaccines over the Janssen adenoviral-vectored COVID-19 vaccine. These actions informed healthcare providers and policy makers and protected and informed the public.

Biosketch



Julia Stowe

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Dr Julia Stowe has worked at UK Health Security Agency since 1999 on vaccine effectiveness and post-licensure epidemiological vaccine safety studies addressing pertinent vaccine safety concerns using routinely collected and electronic healthcare data. Routinely collected and electronic healthcare data is an indispensable tool for epidemiological research but especially in vaccine safety surveillance. These databases can never be used without the consideration of a great number of factors specific to the disease and vaccine. Her PhD assessed the methodological challenges in post-licensure vaccine safety studies and the epidemiological methods employed to quantify a risk, if any, of an adverse event after vaccination. These methods are employed to address the many sources of bias that are inherent when studying such complex conditions in a challenging setting.

Many of the epidemiological challenges are unique to vaccine safety surveillance due to a number of factors and methods employed in the surveillance of therapeutic drugs cannot be automatically transferred. These challenges and the need to be able to respond to vaccine safety concerns in a timely and methodological robust manner need to be balanced. Julia has expertise in the use, implementation and management of large electronic datasets and has worked on many high-profile studies. She manages, designs, analyses and reports using these data carrying out epidemiological studies. She has also led the development of research proposals, writing scientific reports and papers for publication and presented epidemiological findings nationally and internationally at meetings and conferences.

Biosketch

Sylvia Taylor

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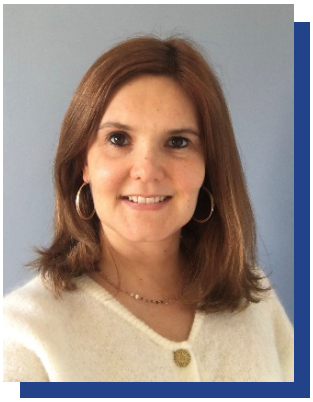
Sylvia Taylor, PhD MPH MBA is an infectious disease epidemiologist and currently Head of Medical Evidence for AstraZeneca's Vaccines and Immune Therapies Unit that was formed in November 2021.

She is passionate about vaccines and preventive interventions for infectious diseases and has spent more than 20 years working on related global health initiatives in both the private and public sector. She initially joined AstraZeneca in 2020 as the lead epidemiologist for AstraZeneca's COVID-19 vaccine program, playing a key role in the distribution of >3 billion vaccine doses worldwide.

She was previously also a senior epidemiologist for GlaxoSmithKline Vaccines, leading epidemiology strategy/activities for late and early-stage vaccines, including HIV, Ebola, TB, HPV, RSV, and Streptococcus Pneumoniae, over a period of 8 years. She has additionally worked as a Senior Technical consultant for the United Nations' International Organization for Migration, collaborating with the US Centers for Disease Control on community-based surveillance among Venezuelan migrants in Colombia, and as a research scientist at the Institut Pasteur in Paris, with focus on epidemiology and prevention of HIV, TB, and Hepatitis C. Originally from the United States, she has spent the last 17 years working/living abroad, including in Belgium, Cameroon, Cambodia, Colombia, Egypt, England, France, and Peru. During 2017-2019, while on sabbatical in Cameroon, she completed a TRIUM Global Executive MBA – a joint program with the London School of Economics, HEC Paris, and New York University Stern School of Business – and worked on several business development projects in Cameroon, China, and Europe.

Biosketch



Laurence Torcel Pagnon

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Laurence Torcel-Pagnon is an Epidemiologist (MSc). She has been working in industry on vaccine preventable infectious diseases for 15 years collaborating in several epidemiological studies and international projects. For the last 10 years, she has been more specifically engaged in European and worldwide public-private partnerships (ADVANCE, DRIVE, COVIDRIVE, GIHSN, BeCOME), co-leading the development of large Real World Evidence platforms for disease surveillance and vaccine effectiveness monitoring (Flu, COVID, RSV and other respiratory viruses). She has co-developed governance guidance and open data frameworks to foster multi-stakeholder collaborations between Public health institutes, Regulatory authorities, Academia, International organizations and vaccine companies for evidence generation and public health benefit. She is acting as Executive Officer at the Foundation for Influenza Epidemiology supporting the Global Influenza Hospital Surveillance Network.

Currently, Laurence is coordinating the evidence generation strategy for Sanofi influenza vaccines (licensed products), working in close collaboration with internal experts/functions and maximizing collaborative approaches with external stakeholder networks and platforms.

Biosketch

Fran Van Heuverswyn

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Fran Van Heuverswyn is the Project Manager of Flanders Vaccine, a non-profit organisation, working cross-sectoral (academic, industry, government) to foster collaborations within the field of vaccines and immunotherapeutics. Fran leads the organisation and her primary responsibilities encompass the daily management, coordination, and execution of projects pivotal to the R&D of preventive and therapeutic vaccines within the veterinary and human field.

She has a background in Biomedical Science and obtained a PhD in 2007 at the University of Montpellier II, France. She reported for the first time the discovery of HIV-1 group O related viruses in wild gorillas in south west Africa, indicating the precursor of HIV-1 group O viruses in humans. Further, she holds a degree in Third World Studies – Biology and a Master in Biological Science from the University of Ghent in Belgium. She is author or co-author on several peer-reviewed journal articles, including Nature and Science.

She has more than 15 years of experience working in several domains related to microbiology, infectious diseases and vaccines. At BioMaric NV, Belgium, she contributed to advanced HIV diagnostics and she has played a prominent role as project officer for the production of reference materials and the standardization of practices within the microbiological field at the European Commission, Joint Research Centre, Geel, Belgium.

Biosketch

Joris Vandeputte

Past President, IABS
Belgium

Joris Vandeputte was elected President of IABS (International Alliance for Biological Standardization) in June 2016. He is founding member of IABS-EU the European affiliate of IABS. IABS-EU implements the objectives of IABS at European level. IABS-EU is partner of the EU IMI (Innovative Medicines Initiative) projects ZAPI and VAC2VAC (www.IMI.eu, www.zapi-imi.eu, www.vac2vac.eu).

IABS hold its founding congress in Lyon in 1955. It is the global independent platform, interface, where stake-holders meet for exchange of science and issues related to vaccines, cell and gene therapy and human Biotherapeutics. IABS stimulates consensus building which might eventually be translated in regulatory frameworks and advises to decision makers.

Joris Vandeputte is also founder and president of TRIVAROP, a public affairs consultancy advising companies and associations in the area of global healthcare. Joris has more than 40 years industry and international organisation's experience in vaccines, conceiving and developing vaccine policies at global level and towards developing countries in particular. Working with European institutions and policy-makers on innovation, health and development is his main activity.

As a virologist at Ghent University (1976-1980), Joris discovered H1N1 flu as a pathogen for swine leading to a better understanding of H1N1 as a zoonosis. After his assignment as Veterinary Officer to control animal diseases in Belgium

and the EU, Joris joined Institut Mérieux animal health which became Rhône Mérieux and later on Merial, where he occupied leading positions in global vaccine development, strategy, regulatory affairs, marketing and production,for animal vaccines and flu vaccines.

In 2001 he joined The Vaccine Fund, where he coordinated relations with European institutions which led to substantial funding by the EU and European governments to GAVI. At Tuberculosis Vaccine Initiative (TBVI) in Lelystad, the Netherlands, Joris developed, with EU institutions, a financial and strategic framework about funding translation of innovation into vaccines for tuberculosis which would be accessible to global markets.

Joris is consultant for international organisations with particular emphasis on zoonoses, one Health approaches and health in developing countries.

Biosketch

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