Safety by Numbers

Highlighting collaboration and data to support vaccine safety communication

This newsletter is produced by: Global Vaccine Data Network.

Collaborating partners: VAC4EU, Institute for Vaccine Safety, Brighton Collaboration, The Task Force for Global Health, Vaccine Confidence Project

News & updates

Shabir A. Madhi awarded Albert B. Sabin Gold Medal

Image credit: Sabin Vaccine Institute

On 18 April, the Sabin Institute presented the Albert B. Sabin Gold Medal, one of the highest recognitions for vaccinologists globally, to Drs. Keith Klugman and Shabir Madhi for their seminal combined contributions to the development of vaccines against pneumonia and diarrheal disease – major causes of death in children in low- and middle-income countries (LMICs).

Klugman and Madhi's research helped pave the way for the introduction of lifesaving vaccines in public immunisation programs – including the pneumococcal conjugate vaccine where their findings were pivotal in influencing vaccination policy in many LMICs.

Madhi heads South Africa's widely respected South African Medical Research Council (SAMRC) Vaccines and Infectious Diseases Analytics Research Unit (Wits VIDA) and is a professor of vaccinology at the University of the Witwatersrand.

Read more on the Sabin Vaccine Institute website.

Lessons learned and key recommendations from the COVAX Vaccine Safety Working Group

The Vaccine Safety Working Group (VSWG) of COVAX was formed in November 2020 with representatives and consultants representing multiple stakeholders, including Brighton Collaboration, Developing Countries Vaccine Manufacturers Network (DCVMN), International Federation of Pharmaceutical Manufacturers and Associations, World Health Organization, and the Coalition for Epidemic Preparedness Innovations (CEPI). Its primary objectives were to function as an open source of information for vaccine developers, to resolve common vaccine safety cross-project questions and challenges at speed, and to facilitate coordination within the ecosystem to maximise impact.

The Working Group published its key recommendations in BMJ Global Health: Collaboration within the global vaccine safety surveillance ecosystem during the COVID-19 pandemic: lessons learnt and key recommendations from the COVAX Vaccine Safety Working Group.

Dr. Eileen Farnon joins Brighton Collaboration as Research Director

The Task Force for Global Health welcomes Dr. Eileen Farnon as Brighton Collaboration's new

Research Director. Dr. Farnon, who is trained in clinical infectious diseases, tropical medicine, and applied epidemiology, brings more than 20 years of experience in public health, including outbreak response and clinical research and development, to the Brighton Collaboration and the SPEAC project.

Dr. Eileen Farnon, Research Director, Brighton Collaboration

Brighton Collaboration is now on LinkedIn!

Follow the Brighton Collaboration page for vaccine safety news and updates from our global community.

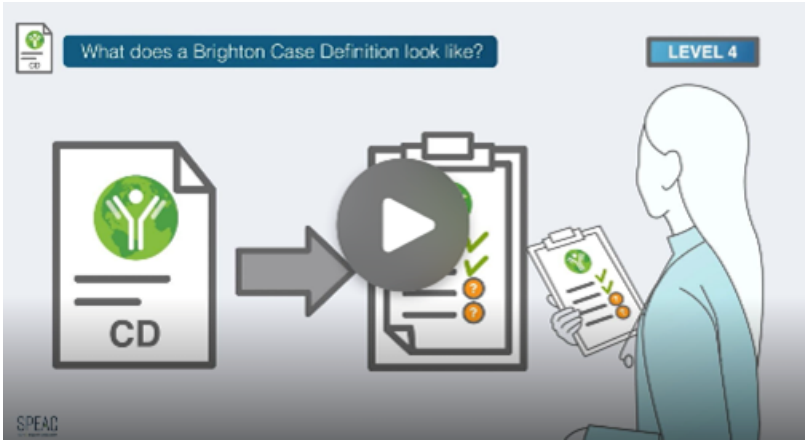
SPEAC

Video: What is a Brighton Case Definition?

Since its founding in 2000, Brighton Collaboration has developed more than 80 Brighton Case Definitions for adverse events following immunisation (AEFI) and adverse events of special interest (AESI). The case definitions are designed to support vaccine safety studies across the entire lifespan of a vaccine.

You may be wondering: *How is a Brighton Case Definition unique? What do the levels of certainty mean? Which situations are and are not covered by Brighton Case Definitions? How is a Brighton Case Definition developed, and why is it trusted?*

Find answers to these questions and more in the video, Brighton Case Definitions, developed and narrated by Dr. Barbara Law. Dr. Law is a paediatric infectious disease subspecialist who headed Canada's vaccine safety program from 2004–2015. She is an active member of the Brighton Collaboration and served on the Brighton Science Board as both a member and a chairperson for many years. She currently heads the SPEAC project's tools and resources work, which includes developing Brighton Case Definitions as well as tools to help apply them. This is the first in a series of videos from the SPEAC project that will be shared with the broader vaccine safety community.



SPEAC experts join International Neonatal and Maternal Immunization Symposium (INMIS)

Three members of the SPEAC Executive Board participated in INMIS in Costa Rica. Dr. Flor Muñoz, the chair of the organising committee of INMIS, presented the SPEAC project during a session focused on the challenges and implementation of pregnancy registries. Dr. Manu Chaudhary presented a poster titled, *Burden of Lassa Fever Disease in Pregnant Women and Children and Options for Prevention*, and led part of the Research Master Class, where she presented the SPEAC Project's landscape review of Chikungunya disease burden and vaccine development in children and pregnant persons. Dr. Andy Stergachis spoke on an expert round table on the topic, *Novel Safety Surveillance of Vaccines in Pregnancy Post-Licensure/Authorization in Low- and Middle-Income Countries*. The Maternal Immunization Working Group, which Dr. Muñoz

also chairs and Dr. Chaudhary and Dr. Stergachis are members, also met during the conference to discuss publications and the group's next steps.

From left to right: Andy Stergachis, Manu Chaudhary, and Flor Muñoz

SPEAC experts join the World Vaccine Congress

The World Vaccine Congress was held in Washington, D.C. from April 1–4, 2024. The SPEAC Project's Scientific Director Dr. Bob Chen, Research Director Dr. Eileen Farnon, and Digital Transformation Lead Dr. Dale Nordenberg, joined more than 5,000 other participants to explore the conference theme of *R&D and Strategic Partnering for the Global Vaccine Industry*.

In the vaccine safety track, Bob Chen and Dale Nordenberg presented on the SPEAC Project's work with Brighton Collaboration Case Definitions (CDs) and the digital transformation of SPEAC products for pandemic preparedness. They reflected on recent and current challenges, such as the development of multiple CDs for the same AESI, the need to update interim CDs, and the use of diverse data platforms in different settings. They shared progress toward improved digital safety services to facilitate the harmonisation of approaches across studies through the SPEAC Safety Portal, an online platform for vaccine safety operations and services. The SPEAC Safety Portal is currently under development as part of the SPEAC Project.

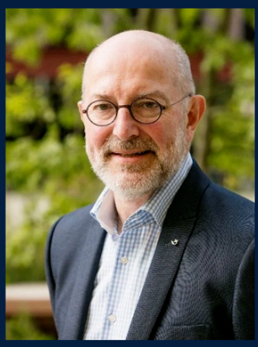
From left to right: Daniel Salmon, Karina Top, Jim Buttery, Eileen Farnon, Bob Chen, and Dale Nordenberg

VACCINE CONFIDENCE PROJECT™

Building trust, managing risk around vaccines: from trials to delivery

Applications closing soon

Short course: 9–12 July 2024



Professor Pierre Van Damme

Professor Heidi Larson

Vaccine Confidence Project

London School of Hygiene & Tropical Medicine

Universiteit Antwerpen

This 3.5 day short course will equip you with best-in-class knowledge, skills and tools for:

1. Identifying drivers of vaccine confidence
2. Measuring and monitoring public perceptions of vaccines
3. Rebuilding vaccine trust

Find out more and register here:

Global Vaccine Data Network®

GVDN Symposium 2024 and the GCoVS Project

Titiro whakamuri, kōkiri whakamua

Look back and reflect, so you can move forward

In April, GVDN held a Symposium at Les Pensières Center for Global Health in Annecy, France. The purpose was to reflect on our work with the Global COVID Vaccine Safety (GCoVS) Project* to date, explore valuable lessons we learned along the way so we can continue to grow and excel, and to share and discuss initial study data. The meeting included representatives from sites participating in the project, collaborators, and the U.S. CDC.

We sincerely appreciate each person, both present and those who were unable to join us, for their invaluable contributions to Symposium 2024. Together, we fostered an environment of learning, collaboration, and innovation that will continue to resonate beyond the Symposium walls.

The rapid cycle analysis (RCA) participating sites and the GCC team have been working closely to test multi-country RCA analyses. Multi-country collaboration is an exciting milestone, aiming to increase study population size and diversity. RCA uses large sample sizes and sequential analyses to detect rare signals that may not have been identified in clinical trials.

Data from study sites participating in the GBS, myocarditis/pericarditis, and VITT post-COVID-19 vaccination association studies has been received by the Global Coordinating Centre (GCC). These are being analysed and will undergo the GVDN Results review process for quality assurance before manuscripts are written and published.

Early data from sites participating in the maternal and neonatal immunisation COVID-19 vaccination safety study has been received by the GCC. A new protocol to identify background rates for maternal and neonatal outcomes is under development. Early data from vaccine mediated enhanced disease (VMED) study sites has also begun to arrive at the GCC.

*This project is supported by the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totalling US$10,108,491 with 100% funded by CDC/HHS. The contents are those of the author and do not necessarily represent the official views of, nor an endorsement, by CDC/HHS, or the U.S. Government. For more information, please visit cdc.gov.

The world's largest vaccine safety study

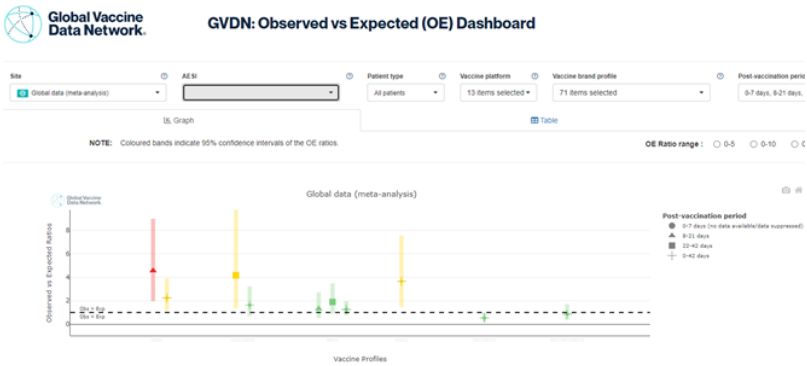
Earlier this year, the paper *COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network (GVDN) cohort study of 99 million vaccinated individuals* was published in *Vaccine*.

Ten GVDN member sites in eight countries analysed data from national or regional healthcare databases covering 99 million people from Europe, Asia, North and South America, and Oceania. Meta-analyses of the observed rates of adverse events of special interest after COVID-19 vaccine introduction compared with the expected (background) pre-COVID-19 vaccine rates established in the GVDN Background Rates Study.

Release of the interactive Observed vs. Expected Dashboard on the GVDN website accompanied the publication. GVDN Co-Director Dr. Helen Petousis-Harris stated, "By making the data dashboards publicly available, we are able to support greater

transparency, and stronger communications to the health sector and public."

Publication of the paper received widespread coverage across multiple media platforms and is in the top 5% of all research outputs tracked by *Altimetric*.



Follow GVDN on LinkedIn

Visit the GVDN LinkedIn page and click on the "Follow" button to receive information and updates from the global immunisation community.

VAC4EU
VAccine monitoring Collaboration for Europe

As the first wave of post-authorisation safety (PAS) studies reach completion, VAC4EU is entering a busy period beginning new protocols, attending events, and publishing manuscripts. They are very proud to announce the publication of three manuscripts from the Covid Vaccine Monitor project (CVM) this year:

- Safety monitoring of COVID-19 vaccines in persons with prior SARS-CoV-2 infection: A European multi-country study (Ciccimarra et al.)
- Frequency and timing of adverse reactions to COVID-19 vaccines; A multi-country cohort event monitoring study (Raethke et al.)
- A comparison of four self-controlled study designs in an analysis of COVID-19 vaccines and myocarditis using five European databases (Schultze et al.)

CVM was an European Medicines Agency (EMA) sponsored extension of the Early COVID-19 Vaccine Monitor (ECVM) project conducted by the European Union Pharmacoepidemiology & Pharmacovigilance Research Network in collaboration with VAC4EU. The research conducted in CVM built upon this body of work by focusing on populations of special interest and using primary data collection. Over 680,000 vaccinated people were approached about vaccine-related side effects. Available pseudo-anonymised European electronic health records were also used to efficiently assess and quantify associations between selected adverse events and COVID-19 vaccinations. Finally, the project evaluated methodologies used in vaccine safety monitoring, aiding in future study conduction. Links to all protocols can be found on the VAC4EU website and all deliverable reports are available on the VAC4EU Zenodo community.

VAC4EU has had representation at a variety of external meetings and events so far in 2024. On March 26th and 27th, the PROMISE consortium held their final event at the Belgian Royal Academies of Medicines in Brussels, where VAC4EU President Miriam Sturkenboom represented VAC4EU in a panel session on respiratory syncytial (RSV) surveillance with other key opinion leaders in Europe. On the 22nd through the 25th of April, Miriam also represented VAC4EU at the GVDN Symposium. She will also represent VAC4EU at the Get Real Institute Annual Conference, the ISoP Mid-Year Symposium, and Vaccines Europe along with Gianmarco di Mauro.

In other news, the VAC4EU Secretariat is busy preparing for the 9th annual General Assembly Meeting on the 21st of May in Bordeaux, where they will welcome 47 members and another 42 online. The programme will feature plenary network updates, an update on strategy, as well as a symposium titled “How to monitor effectiveness and safety vaccines in the future?” featuring guest speakers from multiple institutions including the

European Centre for Disease Prevention and Control (ECDC) and the EMA. The event and dinner are co-organised and hosted by the University of Bordeaux and SIGMA.

The Africa Infodemic Response Alliance, a WHO-hosted network

The Africa Infodemic Response Alliance (AIRA) is Africa's network to share safe, proven facts on health and to counter dangerous health misinformation.

A first of its kind regional network, AIRA brings together fact-checking and media organisations, big data, AI and innovation bodies, and leading inter-governmental and non-governmental organisations working in public health to respond to infodemics.

Viral Facts Africa is the public face of the Alliance, producing fact-based health information, fact checks, debunks and misinformation literacy content for AIRA members and partners.

Their weekly *AIRA Infodemic Trends Report* provides key highlights and operational recommendations based on recent social listening data from Africa.

Read more

8th World One Health Congress

20–23 September 2024

The Congress foresees four days of an outstanding, exceptional, and forward-thinking agenda, which includes parallel tracks addressing one health science, antimicrobial agents and resistance, and science policy interface, amongst others.

It will enable discussing major One Health challenges, as well as sharing research data and policy developments. Above all, it will provide a great opportunity to look at global One Health science and policy through an African lens.

Read more

ISPE 16th Asian Conference on Pharmacoepidemiology

12–14 October 2024

This Conference is hosted in collaboration with the Japanese Society of Pharmacoepidemiology. The synergy between between the JSPE and ISPE underscores the importance of international collaboration in addressing the complex challenges facing health and healthcare today.

The conference aims to foster a dynamic exchange of ideas, cutting-edge research findings, and best practices that will contribute to the advancement of our field.

Read more

EUROPEAN PUBLIC HEALTH CONFERENCE

17th European Public Health Conference

12–15 November 2024

The 2024 conference theme, *Sailing the waves of European public health: exploring a sea of innovation*, encapsulates the collective mission.

Just as explorers once set sail to discover new worlds, public health professionals will embark on a journey of innovation and discovery in the field.

The conference organisers seek to push the boundaries, discover new approaches, and chart the course for the future of public health in Europe.

Read more

Spotlight

Q&A with SPEAC Expert, Dr. Esperança Sevene

Dr. Esperança Sevene is an Associate Professor of Clinical Pharmacology and the Coordinator of the Doctoral Program in Biosciences and Public Health at the Faculty of Medicine, Eduardo Mondlane University (UEM) in Mozambique. She facilitates the SPEAC project's DSMB (Data and Safety Monitoring Board) training course and supports SPEAC active vaccine safety surveillance work.

Most of her research has focused on pharmacovigilance, particularly drug and vaccine safety in pregnancy and maternal health, including preeclampsia, access to treatment, and mother satisfaction of care.

Dr. Sevene has served on DSMBs for TB, HIV, and malaria related clinical trials. "It was an amazing experience for me to be involved in the DSMB for the pilot implementation of the malaria vaccine because I had seen the vaccine through phases 2A, 2B, 3, and then through phase 4."

Read more about Dr. Sevene's journey from graduation as a Doctor of Medicine, attaining a Master of Pharmacology, training in clinical trials and pharmacovigilance, and completing a PhD in the Q&A with SPEAC Expert, Dr. Esperança Sevene.

Seen some interesting research? Maybe something awesome is happening in your line of work? Or do you want to celebrate a recent milestone? Whatever it is, send your contributions to the Safety by Numbers Editorial Board.

Respond

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