Safety by Numbers

Highlighting collaboration and data to support vaccine safety communication

This newsletter is produced by: Global Vaccine Data Network. Collaborating partners: INSIS, Brighton Collaboration, The Task Force for Global Health, VAC4EU, Institute for Vaccine Safety, Vaccine Confidence Project

News & updates

Detecting and addressing false information

Detecting false information can be difficult. Often, people jump to understanding it before assessing rigour or accuracy of the information. The source, content, reputation, and personalities all play a role.

Hot tips for recognising manipulative techniques in vaccine misinformation

People should look for logical fallacies like the *appeal to fear*, *false authority*, or *false dichotomy*. Manipulators often push black-and-white thinking ("100% safe or 100% dangerous") to misrepresent the nuanced reality of vaccine safety. Here is a great reference on how to identify and address common logical fallacies in the healthcare setting.

Spot the 'Fallacy Flashcards'

Identify the 'Rogue scientist effect'

Beware of outlier voices with limited or no relevant expertise who claim to have "secret" insights. This classic technique relies on a single "maverick" to

sow doubt against a consensus built by experts across the field (*false equivalence, fake experts)*.

Watch for 'Cherry picking'

Misinformers often highlight rare side effects or out-of-context studies, ignoring the breadth of evidence. If only a small fraction of studies or bad quality articles are cited while ignoring the bulk of the data, cherry-picking is likely in play.

Recognise the 'Fear bomb'

Emotional language or frightening claims (“DNA contamination” or “Turbo Cancer”) aim to provoke alarm rather than inform. Scientific claims should come with data, not dramatics.

Decode the 'Back in my day' argument

Nostalgia is often misused to suggest older methods were safer, implying innovation is inherently risky. Be wary of arguments that lean on the past as “better” without evidence supporting it.

Beware of 'Complex scenarios simplified to blame'

Misinformation often boils down complex issues into single causes, neglecting the broader scientific context. Be cautious when blame is disproportionately focused on vaccines without consideration for other health or environmental factors.

Look for 'Secret knowledge' and 'Misinformation claims of censorship'

Conspiracy theories often appeal to hidden knowledge or claim that “the truth is being suppressed.” Be wary of arguments that rely on secrecy or the idea that “mainstream” science is hiding something.

Cross-check for 'Data misinterpretation'

Manipulators often use misunderstood scientific terms or improperly applied statistics to create a sense of legitimacy. Ensure claims are backed by properly interpreted data from reliable sources.

By keeping an eye out for these red flags, scientists and health professionals can better address misinformation, protecting public trust in vaccines and strengthening evidence-based discussions. Evidence shows that highlighting the flaws in arguments is an effective technique to counter misinformation.

Tips for pointing out flaws in misleading arguments

Here's a quick guide on how to respectfully point out flaws in an argument when speaking with someone who has encountered bad information:

Ask questions to encourage critical thinking
Gently ask questions like, "What sources did you come across?" or "How does that information fit with what we know from research?" This invites them to think critically without feeling attacked.

Separate the claim from the facts
Break down the claim and compare it to verified data. For example, "That sounds concerning; let's see what studies say about that," then provide reliable, fact-checked information.

Highlight logical inconsistencies
Politely point out contradictions, such as, "If vaccines caused widespread harm, wouldn't we see

it reflected in large studies across many countries?" This exposes flaws without directly calling their view 'wrong.'

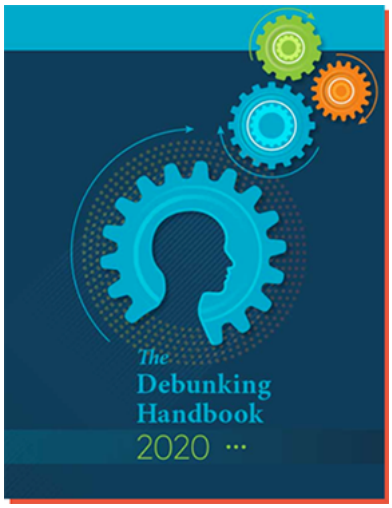
Share analogies for perspective
Use relatable analogies to clarify the flaw in their logic, such as, "Just as a single storm doesn't disprove climate change, a single case doesn't mean vaccines are unsafe."

Empathise and show understanding
Acknowledge their concerns first ("I understand why that could sound worrying"), then follow with evidence-based information, creating an environment for open conversation.

And:

- Pre-bunk misinformation to inoculate susceptible audiences and build resilience (first line of defence).
- If you have to repeat a myth, ensure to include a correction.
- Debunk misinformation often and repeatedly using evidence-based methods.
- Dealing with social media companies....we can only try.

These tips can help guide people toward science-backed insights without putting them on the defensive, encouraging curiosity over confrontation.



The Debunking Handbook 2020

This is an essential handbook for engaged citizens, policymakers, journalists, and other practitioners. Written by a team of 22 prominent scholars of misinformation and its debunking, it represents the current consensus on the science of debunking. *The Debunking Handbook 2020* is available in 20 languages and can be downloaded from the George Mason Center for Climate Change Communication website.

Using psychology to understand and fight health misinformation

The American Psychological Association (APA) consensus statement describes the best available psychological science on misinformation, particularly as it relates to health. It offers eight specific recommendations to help scientists, policymakers, and health professionals respond to the ongoing threats posed by misinformation.

Written by: Helen Petousis-Harris, PhD
Associate Professor, University of Auckland

Advancing global collaboration: INSIS network update

Since its establishment in 2021, the International Network of Special Immunization Services (INSIS) has undergone significant growth, evolving into a dynamic consortium dedicated to advancing research and innovation in vaccine safety. INSIS is excited to report that the network now encompasses 21 collaborating sites across 10 countries and five continents. This expansion not only underscores their commitment to excellence but also enhances their ability to tackle global health challenges.

INSIS recently convened for a productive Joint Steering Committee meeting in Montreal, QC, on September 30 and October 1. The meeting was well-attended, with nine participants joining in person from Canada, the United States, Italy, Sweden, and South Africa, alongside 19 virtual participants.

The meeting provided a valuable opportunity to assess progress on INSIS' two primary projects, funded by the Coalition for Epidemic Preparedness Innovations (CEPI). The first initiative focuses on understanding biological mechanisms underlying myocarditis and vaccine-induced immune thrombotic thrombocytopenia (VITT) post-COVID-19 vaccination. The second aims to enhance capacity for vaccine safety evaluation in low- and middle-income countries (LMICs) through a mixed methods approach and sample collection pilot study. Despite administrative delays, the projects are progressing with initial results expected early in 2025.

Additionally, discussions included identifying key priorities that will form the basis for a five-year strategic plan that will aim to ensure INSIS' continued growth and sustainability, while cementing its role in the vaccine safety landscape.

For the latest updates on INSIS, please follow their LinkedIn page. If you are interested in joining the INSIS Network or becoming a partner, kindly reach out to them at insis@ualberta.ca.

From left to right: Amanda Wilson, Sara Moradipoor, Richard Kennedy, Rebecca Chandler, Kimberley Gutu, Karina Top, Paolo Palma, Inna Ovsyannikova, and Joann Arce

COVID-19 vaccines and neurological risks: What the CANVAS-COVID study revealed

A recent publication in the journal Vaccine led by Karina Top and colleagues at the Canadian National Vaccine Safety Network examined neurological events following COVID-19 vaccination. The CANVAS-COVID study employed participant-reported active surveillance using email surveys to track adverse events after vaccination compared with unvaccinated controls, and captured neurological symptoms like numbness, tingling, loss of smell or taste, facial paralysis, and seizures. Data were collected from a large cohort of 1.3 million participants, including recipients of mRNA vaccines (BNT162b2, Pfizer/BioNTech; mRNA-1273, Moderna) and ChAdOx1 (AstraZeneca and Serum Institute of India).

The results revealed that neurological events were rare (<1/1000) across all vaccine types. However, participants who received the ChAdOx1 vaccine had a slightly higher risk of reporting neurological symptoms after the first dose, compared with unvaccinated controls. The most common neurological event reported was anaesthesia/paraesthesia (numbness or tingling), which was significantly higher among ChAdOx1 recipients than controls. Recipients of two doses of mRNA-1273 were also at higher risk of anaesthesia/paraesthesia after dose two than controls, but there was no statistically significant increase in neurological events among other mRNA vaccine recipients (doses one, two, or three) compared with unvaccinated participants.

Notably, the study also found a decreased risk of COVID-19-related symptoms like loss of taste or smell among mRNA vaccine recipients compared with unvaccinated individuals. Very rare events such as Bell's palsy and Guillain-Barré syndrome were also reported among vaccinees after mRNA and ChAdOx1 vaccines, respectively, consistent with safety signals identified in other surveillance systems.

Participant-based reporting (also known as cohort event monitoring) can be implemented quickly to monitor new vaccine programmes to detect and

characterise vaccine safety signals when deployed at scale. The reported association of anaesthesia/paraesthesia with COVID-19 vaccination warrants further study. Studies such as CANVAS-COVID can help to ensure continued safety of vaccination programmes and help to build public confidence in vaccine safety.

SPEAC expands digital tools for vaccine safety in the digital era

Expanding access to vaccine safety resources

In recent months, the Safety Platform for Emergency vACcines (SPEAC) has released several significant online resources to strengthen global vaccine safety frameworks. September marked the publication of a comprehensive list of potential adverse events of special interest (AESI) for mpox, alongside a *Cohort event monitoring (CEM) protocol template for active safety surveillance post-mpox vaccination*, publicly available on Zenodo. This template serves as a vital tool for public health organisations and researchers, supporting consistent tracking of potential vaccine safety issues.

Continuing these efforts in October, SPEAC released an AESI list specific to the Marburg virus, further advancing the groundwork for effective safety monitoring in response to emerging infectious disease threats. Together, these resources equip health authorities with valuable, standardised tools to identify and respond proactively to vaccine safety concerns.

SPEAC participation at ISoP Montreal 2024

SPEAC and Coalition for Epidemic Preparedness Innovations (CEPI) members took part in the 23rd International Society of Pharmacovigilance (ISoP)

meeting in Montreal, which focused on global perspectives on pharmacovigilance in the digital age and advanced therapeutics. A plenary session chaired by CEPI's Rebecca Chandler titled *Preparedness for the next disaster* highlighted critical aspects of vaccine safety and evidence generation. Eileen Farnon presented on tools to support robust safety evidence, the Global Vaccine Data Network (GVDN) representative Bruce Carleton underscored the role of genomics in understanding vaccine safety, CEPI's Danielle Craig discussed regulatory preparedness, and CEPI's Alexander Precioso focused on building pharmacovigilance capacity in the Global South.

From left to right: Comfort Ogar, Bruce Carleton, Esperança Sevene, Andy Stergachis. Rebecca Chandler, Alexander Prescioso, Miriam Sturkenboom, and Eileen Farnon

During the poster sessions, presentations highlighted SPEAC's contributions to global pharmacovigilance. SPEAC members Esperança Sevene and Andy Stergachis presented a *Landscape assessment of active safety surveillance of novel vaccines in low- and middle-income countries (LMIC)*. The aim of the study was to identify existing active safety surveillance systems and their components in LMIC, as well as those that are in the planning stages. Furthermore, they characterised their strengths and limitations and determined how they might be used or adapted to monitor new vaccines.

Representing the wider SPEAC team, Farnon showcased the poster titled *Preparing for vaccine adverse events of special interest-X (AESI-X): A standardized approach for novel vaccines*. The objective was to facilitate the development of a

consensus process among key vaccine safety stakeholders for developing standardised case definitions for AESI-X early in the outbreak response.

Esperança Sevene (left) and Andy Stergachis

Eileen Farnon

Global Vaccine Data Network®

18th Vaccine Congress in Lisbon, Portugal

Hazel Clothier and Jim Buttery represented the GVDN at the 18th Vaccine Congress in early September with an oral presentation on *The Global Vaccine Data Network™: A multinational collaboration generating real-world evidence for safer immunisation*.

Clothier also spoke on *Shifting the dial: Vaccine safety intelligence for informing community conversations* from her work at the Epi-Informatics Centre for Health Analytics at the Melbourne Children's Campus in Australia. From his work at the Murdoch Children's Research Institute in Australia, Buttery presented *Data demonstrating tinnitus as a vaccine-associated adverse event* and a *Description of syndromic surveillance and Australia's system* during the *Roundtable on syndromic surveillance of vaccine-associated adverse events: The need for a new paradigm*.

World Congress of Epidemiology in Cape Town, South Africa

Later in September, Arier Lee and Yannan Jiang attended the World Congress of Epidemiology, presenting the GVDN global studies on COVID-19 vaccines and adverse events of special interest.

Jiang gave an oral presentation on the *COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network (GVDN) signal-detection study*, the world's largest vaccine safety study that established background rates of 13 adverse events of special interest (AESI) in 2015–2019 and evaluated the risk of those AESIs occurring after COVID-19 vaccination immunisation programmes across eight countries. You can read more about the study and results in the paper published in the journal Vaccine.

Yannan Jiang (left) and Arier Lee

Lee's poster presentation *Pioneering a unified platform for comprehensive vaccine safety assessment – The Global Vaccine Data Network (GVDN) initiative* highlighted the pragmatic approach for conducting epidemiological studies globally on COVID-19 vaccine safety within the GVDN framework, which includes harmonised protocols and big data from millions of vaccinated individuals to characterise vaccine safety, promote evidence-based decisions, and increase global vaccine confidence.

'Turbo Cancer' enters mainstream media

The scientifically flawed and biologically implausible internet conspiracy theory about mRNA vaccines dubbed "Plasmid-gate" filled anti-vax echo chambers and lined social media threads of the malign disinformation spreaders. Spouting flawed studies from rogue scientists, dropping fear bombs, and claims of holding secret knowledge (see lead article), their purposeful manipulation of followers and vulnerable bystanders launched 'Turbo Cancer' into mainstream media.

This newly invented medical condition is a theory in search of credible scientific evidence and facts that just are not there. GVDN posted a series of blogs to debunk the false claims and provide the facts for public, health professionals, and scientists.

- Plasmid-gate: Debunking the DNA contamination claims in mRNA vaccines
- mRNA – It's just a messenger, not a mastermind (or How mRNA vaccines are made and why they are very safe)
- 'Turbo Cancer' and mRNA: The myth that defies biology and physics

Spoiler alert – Facts about vaccines and their ingredients

- Vaccines are designed to protect – not harm.
- Vaccines are one of our best defences against virus-related cancers.
- The idea that residual DNA can integrate into human DNA and cause cancer is biologically implausible.
- mRNA remains in the cytoplasm and is degraded after translation; it does not enter the nucleus or integrate into host DNA.
- Any minuscule amounts of residual DNA from vaccine production processes are heavily degraded fragments and pose no risk to human health.
- Regulatory agencies worldwide, including the FDA and WHO, require manufacturers to strictly adhere to Good Manufacturing Practice to ensure residuals and impurities are rigorously removed. Proper tests like qPCR reveal that any residual DNA is well within safety limits set by health authorities.
- Extensive trials and real-world data demonstrate no long-term tissue accumulation or genetic risk.

VAC4EU
VAccine monitoring Collaboration for Europe

Safety of COVID-19 vaccines in people with allergies

In September, *Safety of COVID-19 vaccines among people with history of allergy: A European active surveillance study* (Luxi et al.), was published in the journal Vaccines. The study focused on the safety of different COVID-19 vaccine brands and doses in people with a history of allergy compared to those without using self-reported outcomes collected through an electronic questionnaire across several European countries. The authors concluded, "Any drug or vaccine use carries a risk of severe allergic reactions, yet the benefits of vaccination generally outweigh these potential risks, as shown with the COVID-19 vaccines." This publication was the sixth article from the COVID-19 Vaccine Monitoring (CVM) project published in 2024 alone!

Self-controlled risk interval study design tested for robustness

In July, another CVM article, *Applying two approaches to detect unmeasured confounding due to time-varying variables in a self-controlled risk interval design evaluating COVID-19 vaccine safety signals, using myocarditis as a case example* (Bots et al.), was published in the American Journal of Epidemiology as part of the CVM project. Self-controlled risk interval (SCRI) design is efficient and often used in vaccine safety studies. Only cases of specified adverse events are included. Comparison is between risk and control windows around vaccination within the same person, which controls for stable risk factors within the person. However, this design does not remove confounding by time-varying factors, such as developing COVID-19 infection. Misclassification of outcome and exposure may also occur. The authors used negative control outcomes and quantitative bias analysis to assess the robustness of an SCRI design using COVID-19 vaccines, with myocarditis as the case example.

Safety of COVID-19 vaccines in immunocompromised people

In June, *What is the safety of COVID-19 vaccines in immunocompromised patients? Results from the European 'Covid Vaccine Monitor' Active Surveillance Study"* (Bellitto et al.) was published in the journal Drug Safety. This study actively monitored the safety of COVID-19 vaccines in immunocompromised people with a comparison to non-immunocompromised vaccinees. The study generated evidence about the safety profile of four COVID-19 vaccine brands for a subgroup of vaccine recipients, who are typically excluded from clinical trials and where post-authorisation safety information is limited.

EMA SAFETY-VAC project protocols and reports

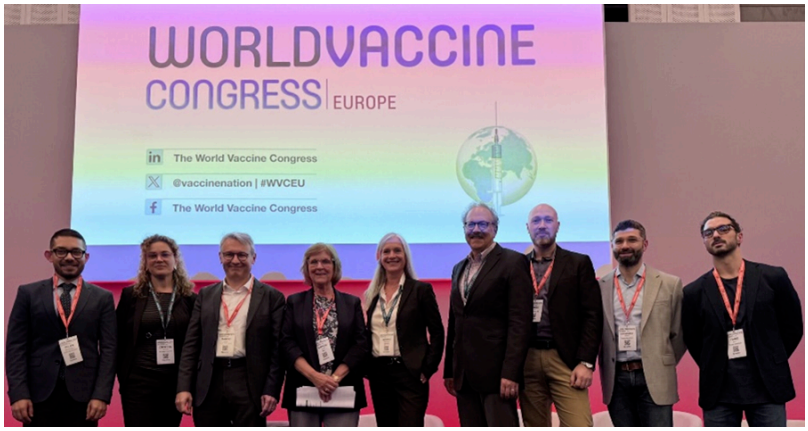
The European Medicines Agency (EMA) ROC18-SAFETY-VAC project, *A framework for the post-authorisation safety evaluation of vaccines in the EU*, is a collaboration between VAC4EU and the European Union Pharmacoepidemiology and Pharmacovigilance (EU PE&PV) Research Network. The primary aim of this EMA-funded project is to assess the feasibility of participating data sources to participate in vaccine safety studies using electronic healthcare databases in European countries through two specific studies.

The first study aims to provide and describe a network of real-world data sources from nine European Economic Area countries for the evaluation of vaccine safety signals and assessment of whether data are fit for the purpose of real-time safety monitoring of vaccine safety studies. The protocol and the first study report were accepted by the EMA. The protocol was published in the HMA-EMA Catalogue, while the first study report was published on the VAC4EU Zenodo community page.

The second study aims to estimate the background and cumulative incidence of the flares of 10 pre-defined autoimmune diseases and analyse the contribution of different data provenances. The protocol for this study was also accepted and published in the HMA-EMA Catalogue. The study report is currently under development. Both studies employ a retrospective, multi-database, population-based cohort design using data from 2017 to the most recent updates. We look forward to reporting more news and highlights from this project.

VAC4EU prominent at the World Vaccine Congress Europe 2024

VAC4EU was well-represented at the World Vaccine Congress Europe 2024, held in Barcelona at the end of October, organising a working group and participating in two panels.



From left to right: Felipe Villalobos, Cristina Rebordosa, Marco Cavaleri, Marion Gruber, Miriam Sturkenboom, Walter Straus, Ruben Rizzi, Gianmarco Di Mauro, and Fabio Riefolo

How to generate regulatory grade RWE [real-world evidence] for vaccines was an interactive working group, organised and moderated by VAC4EU President Miriam Sturkenboom. The group included VAC4EU members, panelists speaking from an industry or vaccine manufacturer perspective, and Marco Cavaleri from the EMA who provided a regulatory voice. The discussion focused on how regulatory-grade RWE could be produced in high- and low-income settings.

Sturkenboom was a panelist in the *Post-authorization safety and effectiveness evaluation of vaccines deployed under emergency use authorization* session, moderated by Walter Straus (Moderna), and in the *Why are public private partnerships so important for vaccine development and how do we sustain them* session, moderated by Hamilton Bennett (Moderna).

The latter focused on how public and private sectors can work together with the Innovative Health Initiative (IHI) and featured IHI Executive Director Niklas Blomberg alongside industry voices.

Miriam Sturkenboom (left) and Niklas Blomberg

VAC4EU was highlighted as an example of how these collaborations can be transformed into a sustainable model that promotes knowledge-sharing and further collaboration.

The conference was inspiring and productive, with equity, access, vaccine production and research, and public-private collaboration emerging as key themes for VAC4EU during their contribution.

World Health Organization

EPI-WIN: WHO Information Network for Epidemics

The Science Translation initiative for better health emergency preparedness

Part of WHO's wider community-centred approach to epidemic and pandemic preparedness, EPI-WIN aims to make scientific information accessible, understandable, and meaningful to all communities during emergencies so that their decisions, policies, and actions are evidence informed.

Based on the outcomes of the 2021 global conference with over 60 communications experts and the public and informal consultation with experts, the Science Translation (ST) initiative is working toward:

- Building a global, multidisciplinary network of entities involved in translating science and knowledge in health emergencies;
- Expanding and developing the EPI-WIN platform;
- Developing capacity building resources for ST in health emergencies, including toolkits and field guides; and
- Strengthening scientific and health literacy, including in non-health sector groups.

Examples of translation 'in action' include regular EPI-WIN webinars, slide sets with insights on a variety of critical health emergency preparedness topics, updates, youth engagement, and the Infodemic Management network.

Read more

Public Health Conference – 2025

10–11 February 2025

The conference theme is Disease Prevention and Control and is intended to bring together and provide a platform for leading academics and scientists in the field of public health, interdisciplinary researchers, practitioners, and educators to exchange and share relevant experiences in their practice, recent innovations, trends, and concerns in their research efforts. The conference will also give participants the time to disclose the practical challenges they encountered and the solutions they discovered in their field investigations in public health.

Read more

World Vaccine Congress

21–24 April 2025

This global event in the vaccine space brings together key professionals from academia, biotech, government, non-profits, and pharma, to discuss advances in vaccine development, production, and distribution.

Delegates can participate in workshops and discussions on the future of vaccine innovation and deployment, access to case studies on new vaccine technologies, regulatory approvals, and successful clinical trials, gain cutting-edge knowledge on vaccine development, and network with industry leaders and potential partners to explore collaboration opportunities.

Read more

EUROPEAN PUBLIC HEALTH CONFERENCE

18th European Public Health Conference

11–14 November 2025

The annual scientific conference on public health issues in Europe offers excellent opportunities to learn from the latest research and practice, to network with experts and colleagues, and to expand professional horizons.

The theme for the 2025 conference is *Investing for sustainable health and well-being*. Abstracts are invited from 1 February to 1 May 2025 for workshops and single presentations in all areas of public health research, practice, policy, and education.

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Suggestions for the newsletter

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.

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Our email provider is changing

Our next Safety by Numbers newsletter is due to be released on 12 February 2025. It will be delivered to your inbox by a new provider, whom we have not yet confirmed. We hope this will not affect your timely receipt of the newsletter. If you do not receive the February 2025 newsletter, please email us at gvdn@auckland.ac.nz.

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