



Vaccine Safety Quarterly

Brighton Collaboration Community News

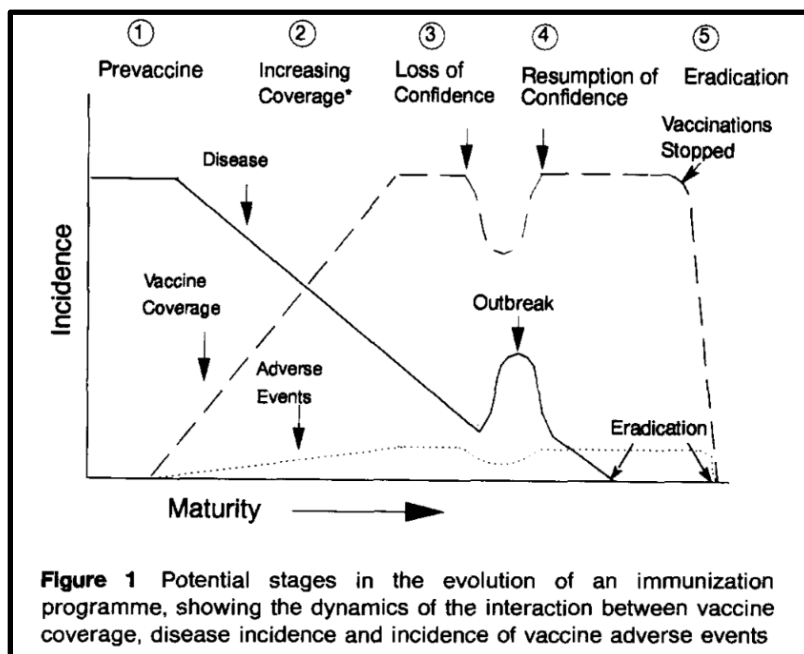
Quarter 4 - 2023

Frederick Varricchio, PhD, MD - *Editor-in-chief*

Nadja Vielot, PhD - *Associate editor*

Vaccine is 40

July 23, 2023 marked the 40th anniversary of the journal *Vaccine*, which was commemorated with a [commentary by long term Editor-in-Chief Gregory Poland and Elsevier executive publisher Nicolette van Dijk](#). The commentary [lists the 50 most cited papers](#) from *Vaccine* over a wide range of subjects, from adjuvants to zoster. Number 23 is the [Brighton case definition of Guillain Barré syndrome \(GBS\)](#). Number 47 is the first paper on the [Vaccine Adverse Event Reporting System \(VAERS\)](#), featuring this often used figure on the stages in the Evolution of Immunization Programs as they mature:



We applaud *Vaccine* and Dr. Poland on 40 Years of Excellence in disseminating cutting-edge research to advance infectious disease prevention through vaccination. We will continue to follow their great work and showcase it here in the Vaccine Safety Quarterly newsletter.

I. UPDATES ON GLOBAL OUTBREAKS

COVID-19

COVID-19 continues to produce variants of the Omicron strain that spread rapidly and widely. JN.1 is currently the most common variant detected in new cases in the United States, having first been detected in October and now comprising over 40% of cases. But HV.1 is increasing and projected to be dominant; see the [CDC website](#) for the latest data. BA.2.86 is also being followed closely because of its high potential to mutate. [Carlos del Rio's latest summary](#) in JAMA (“COVID-19 in the Fall of 2023—Forgotten but Not Gone”) describes the current COVID-19 situation in the US and provides a summary of clinical information.

COVID-19 Vaccine

The US Food and Drug Administration (FDA) has approved two updated COVID-19 mRNA vaccines ([Moderna, Pfizer](#)) to protect against the XBB.1.5 subvariant of the Omicron variant, as well as the EG.5 and BA.2.86 subvariants. A combined COVID-19 plus flu vaccine and a nasal self administered flu vaccine, among others, are being studied.

With the development of novel vaccines comes the duty to rigorously assess vaccine safety. The Brighton Collaboration will continue its collaboration with CEPI to update the [list of possible Adverse Events of Special Interest \(AESI\) \(Updated October 2022\)](#) that may be associated with a COVID-19 vaccine. Case definitions and other tools for assessing COVID-19 vaccine AESIs are available,

COVID-19 Research

Even as the pandemic enters an endemic phase, we will still be dealing with adverse health effects among those who recovered from acute infections. Long COVID-19 continues to affect some individuals long after the virus has been cleared, with up to 200 million cases reported. Unfortunately there is no objective test to evaluate causation of these many symptoms which have been reported to last 3 years

or more. [Long COVID-19 may emerge even after acute Covid appears to have cleared](#), and may lead to [significant activity limitations](#) in the long term. [Long COVID-19 and significant activity limitations](#). The National Institutes of Health (NIH) recently established the [Office of Long COVID Research and Practice](#), which plans to implement clinical trials to study the effects of different interventions and treatment modalities in preventing Long COVID-19 under the [RECOVER](#). Of course there is ongoing research to define the pathogenicity of Covid-19. There are a number of papers that point to mitochondria as the primary point of attack by the virus.

II. VACCINE SAFETY RESEARCH

The BEST Initiative

The US Food and Drug Administration’s Center for Biologics Evaluation and Research (CBER) has formed the [Biologics Effectiveness and SafeTy \(BEST\) Initiative](#) to ensure the safety and effectiveness of biological products. BEST uses novel methods such as artificial intelligence and natural language processing to conduct biologics safety surveillance using real-world data. A distributed network and an innovative methods exchange platform are also envisaged. Several publications have already been approved. See BEST for a list. [A recent publication from BEST](#) evaluated COVID-19 vaccine safety in near-real time using large commercial insurance databases, confirming previously-known safety signals for myocarditis/pericarditis and anaphylaxis following mRNA vaccination. BEST surveillance will continue to identify safety signals of interest that can be explored further. Check out the [BEST Seminar Series](#) for monthly updates on surveillance and real-world data methods.

Adverse Events Monitoring

- [Injection site necrosis after 23-valent pneumococcal vaccination](#)

- [6 unusual side effects of medicines](#): A chemist's point of view

III. VACCINATION AND SOCIETY

Vaccination Intentions and Hesitancy

[An enhanced communication strategy to promote pertussis vaccination among pregnant people in Milan, Italy](#) could provide insights for COVID-19 vaccination communications. Insights from the field of organ donation can inform COVID vaccine promotion programs by [reducing barriers to vaccination for "passive positives"](#), or those who have positive beliefs about vaccination but lack motivation to seek it out. The [Moderna Atlas website](#) includes resources for vaccine providers to improve vaccine confidence among patients. Register for an account to access [Bench2Practice trainings](#) that can promote COVID-19 vaccination in your practice, such as emphasizing the [important role of pharmacists](#) in vaccination and [delivering presumptive vaccination recommendations](#).

Combating COVID-19 vaccine hesitancy requires effective communication of the benefits and risks of vaccination. A contrarian suggestion is that [there should be no response to misinformation](#) because a response risks amplifying the misinformation and suggests a moral equivalency between legitimate science and pseudo-science. Unfortunately, [several physicians have contributed misinformation on social media](#), seemingly legitimizing anti-vaccine perspectives that are not based in science. Meanwhile, the New York Times recounts novel and [imaginative COVID-19 conspiracy theories](#) currently circulating. Providers can rely on the WHO's "[Vaccine safety and false contraindications to vaccines](#)" manual to understand common misconceptions about vaccination.

Governmental vaccination mandates, a long-standing strategy for infectious diseases prevention, are [facing new challenges](#) with growing vaccine hesitancy.

[Religious exemptions](#) and [medical freedoms](#) continue to protect anti-vaccine beliefs and behaviors, and the processes for granting religious exemptions are inconsistent across jurisdictions in the US. In California, a 2019 policy change intended to reduce medical exemptions for vaccination was [successful in this goal, but this benefit was undermined by an increase in children avoiding vaccination requirements](#) by attending school remotely or homeschooling. [Confidence in scientists to act in the public's best interest](#) has decreased since before the COVID-19 pandemic, and over [half of US adults do not plan to receive the new COVID-19 boosters](#) that protect against novel variants. In mid-December [the CDC issued a plea for increased efforts](#) to immunize against Covid, flu, and respiratory syncytial virus as the respiratory infection season in the United States reaches a peak.

Political Vaccinology

As presidential election campaigns gain momentum in the United States, [controversy over the candidates' handling of COVID-19](#) is a hot-button issue.

A proposed NIH program to better understand what health communication works for whom was [paused without explanation](#).

The Nobel Prize in Medicine

Another honor for [Dr. Katalin Kariko](#), whose long and quiet work led to the new generation of mRNA vaccines.

Nobel Prize winners Drew Weissman and Katalin Karikó (Photo by Peggy Peterson). Der Spiegel



Obituary

[Abraham Bergman](#) was a powerful advocate for many childhood health problems and was instrumental in passing the 1974 [Sudden Infant Death Syndrome](#) Act.

Caveat Emptor

Dr. Gregg Semenza, 2019 Nobel Prize Laureate for his work on cellular oxygen regulation, has [withdrawn several publications](#). The publications had already been cited over 750 times.

The president of Stanford University, Dr. Marc Tessier-Lavigne, [withdrew his landmark 2009](#) paper on Alzheimer's disease. Unfortunately, these very public disclosures cast a shadow and doubt on all science and scientists. Paper retractions have increased markedly recently, perhaps in parallel with the [increase in so-called "paper mills"](#), scientific journals known for rapid publishing of low quality or fabricated manuscripts. However, this is not a new phenomenon. In 1923 pharmacologist A.J. Clark lamented [false advertising by makers of proprietary medicines](#), citing a fraudulent tuberculosis treatment that was published in a prominent journal.

Reader, beware! To flex your peer-review skills and learn how to critically assess articles, please join our journal club (details below).

IV. BC MEMBER NEWS & ANNOUNCEMENTS

[Brighton's SPEAC project is now on LinkedIn](#)

Follow the Safety Platform for Emergency Vaccines on [LinkedIn](#) for the latest developments and resources from our team of vaccine safety experts.

[SPEAC Experts discussed Real-World Evidence at IABS conference](#)

SPEAC Executive Board members joined colleagues in Leuven, Belgium at the IABS – Flanders Vaccine RWE Conference, "The Role of Real-World Evidence (RWE) for Regulatory and Public Health Decision Making for Accelerated Vaccine Deployment." The event took place from September 19 – 20, 2023, and was hosted by the International Alliance for Biological Standardization and sponsored in part by CEPI.

[Editorial: SPEAC's Real-World Evidence Framework](#)

Bob Chen shares his reflections on the SPEAC project's Real-World Evidence framework in an editorial originally published in *Safety by Numbers*.

[SPEAC Expert, Dr. Andy Stergachis, awarded first-place poster at ISoP conference](#)

Dr. Andy Stergachis received the first-place poster award at the annual conference of the International Society of Pharmacovigilance (ISoP) in Bali, Indonesia in November 2023. He presented research on the safety, immunogenicity and effectiveness of COVID-19 vaccines for pregnant persons, which was funded by the Bill & Melinda Gates Foundation. Dr. Stergachis and team conducted a living systematic review and meta-analysis of nearly 600,000 pregnant persons who received COVID-19 vaccines.

[Webinar Recording: Sensorineural Hearing Loss \(SNHL\), Lassa Fever, and Vaccines](#)

SPEAC hosted a webinar on September 22 on Sensorineural hearing loss (SNHL) and Lassa fever vaccines. The aim of the event was to review what is known regarding SNHL, Lassa fever disease, and vaccines and to discuss how hearing abnormalities that may occur during clinical trials should be evaluated and monitored. [Watch the recording >](#)

[Beyond COVID Monitoring Excellence \(BeCOME\)](#)

[BeCOME](#) was created to provide a sustainable forum where experts can collectively discuss and develop innovations for post-marketing monitoring of benefits

and risk of vaccines, leveraging the learnings and keeping the momentum of progress made in response to the COVID emergency.

Global Vaccine Data Network

The GVDN recently published a newsletter with one article that speaks to the special vaccine needs of Pacific Islanders. At a meeting in Fiji it was stated that because of geographic distances and ethnic diversity of the islands decisions on vaccine needs and safety should be based on local data. [Read the latest Safety by Numbers newsletter.](#)

Ongoing Case Definition Translations

We are excited to announce that the Brighton Collaboration has begun publishing [Korean translations](#) for our case definitions and associated companion guides. Some have been published previously in [Chinese](#), [Spanish](#), [French](#), and [Portuguese](#).

Vaccines Journal Club

In collaboration with the International Society for Pharmacoepidemiology (ISPE) Special Interest Group (SIG) on Vaccines, the Brighton Collaboration is pleased to continue the Vaccine Safety Journal Club. Members of both organizations are invited to review and discuss the latest research on vaccine safety, from epidemiological methods to qualitative research. The journal club is co-hosted by SIG Chair Jen Gerber and BC member Nadja Vielot of the University of North Carolina. **The next journal club meeting is planned for February 7, 2024 and will be led by Priyadarshani Dharia of Moderna and Elizabeth Bell of Optum.** To receive the virtual journal club link and to receive journal club announcements, please join the mailing list by completing this [Google Form](#).

If you are interested in leading a future journal club session, please contact nadjavielot@unc.edu.

New Brighton Collaboration Publications

- [A Brighton Collaboration standardized template with key considerations for a benefit/risk assessment for the Novavax COVID-19 Vaccine \(NVX-CoV2373\), a recombinant spike protein vaccine with Matrix-M adjuvant to prevent disease caused by SARS-CoV-2 viruses](#)
- [A Brighton Collaboration standardized template with key considerations for a benefit/risk assessment for the Medigen COVID-19 protein vaccine](#)
- [Sensorineural Hearing Loss: AESI Case Definition Companion Guide](#)
- [Anosmia Case Definition](#)

BC Membership

Brighton is looking to expand its membership to strengthen global participation in activities and working groups. Currently, Brighton Collaboration consists of over 1000 members in 108 different countries with the majority of members from the USA, Canada, and India. Please encourage your colleagues to visit our website and [join](#) the Brighton Collaboration.

Brighton Collaboration Website

The BC website is continuously updated with BC news and activities. It also has an archive of BC case definitions and publications on [the new website](#). Please send comments on the new website, and keep an eye out for new content and features on the website as we go forward.

Articles and Comments to the VSQ are welcomed and invited

The VSQ is produced by volunteers. But, there are unavoidable expenses for office supplies, etc. If you would like to help financially with the VSQ, [click here](#) and accept our thanks.

We would like to have a series of groups report their work on vaccines, vaccine safety, etc. What have you done? What are you doing? What would you like to do? Contact Editor-in-Chief Fred Varricchio (varricchio@comcast.net) to contribute.

Subscribe to Vaccine Safety Quarterly:

If you received this VSQ from a colleague and would like to be added to our mailing list, please complete this form: <https://bit.ly/3nPq3>

V. NEW VACCINE SAFETY LITERATURE

A PubMed search for “vaccine, adverse event” yields approximately 200 new articles each month. Here are a few articles that may be of interest to you:

1. Effects on male fertility indicators following infection is a growing area of research, and also a growing source of vaccine hesitancy: [Effect of SARS-Covid-19 Vaccination on Sperm Quality: Systematic Review](#)
2. A telephone-based rapid vaccine adverse event reporting system can improve vaccine safety data collection in resource-limited countries: [Efficacy and feasibility of SMS m-Health for the detection of adverse events following immunisation \(AEFIs\) in resource-limited setting-The Zimbabwe stimulated telephone assisted rapid safety surveillance \(Zm-STARSS\) randomised control trial](#)
3. Ongoing pharmacovigilance activities assess the long-term risks of COVID vaccine-associated adverse events: [Delayed adverse events following COVID-19 vaccination in patients with systemic sclerosis and other autoimmune diseases: a substudy of the COVAD-2 cohort](#)
4. As coadministration of seasonal flu and COVID-19 vaccines increase, post-licensure trials assess the safety of this practice: [A single blinded, phase IV, adaptive randomised control trial to evaluate the safety of coadministration of seasonal influenza and COVID-19 vaccines \(The FluVID study\)](#)

BRIGHTON COLLABORATION LEADERSHIP

Brighton Collaboration Science Board

Here is the [full list of SB members](#) and their qualifications as well as their [Brighton experience and areas of expertise](#).

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