Vaccine Safety Quarterly (VSQ) Spring 2023

Brighton Collaboration 2.0

Frederick Varricchio, PhD, MD - *Editor-in-chief*
Nadja Vielot, PhD - *Associate editor*

Dear Brightonians,

Spring flowers are starting to blossom here in Atlanta. They are a welcome sign that the opportunities to renew and reinvent are ever present. In that theme, I'd like to share background and context for the Brighton Collaboration Safety Platform for Emergency VACcines (SPEAC) Project, which was recently continued and expanded (see also p. 5 of this issue).

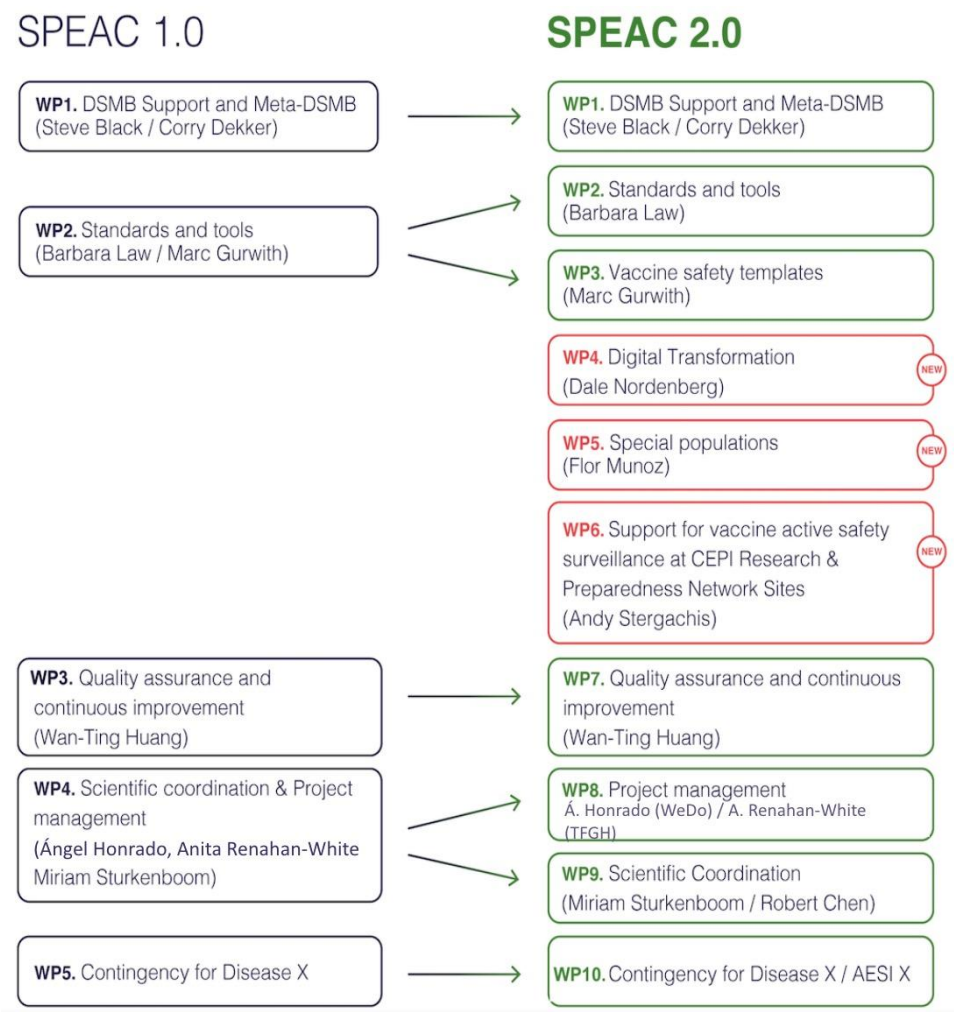
The SPEAC project serves as a bridge between the Brighton Collaboration 1.0 based in Basel, Switzerland and 2.0 based in Decatur, GA, USA. The story started in March, 2014 when the largest Ebola outbreak in history erupted in West Africa. Under extremely challenging circumstances, the World Health Organization (WHO) successfully organized an efficacy and effectiveness trial of a candidate Ebola vaccine using an innovative ring vaccination, open label, and cluster randomized design. In a July 2015 paper, Stan Plotkin et al. argued that Ebola is but one of many deadly human pathogens without a vaccine that demonstrated safety and efficacy in clinical trials. A "Global Vaccine-Development Fund" was needed to invest in the various clinical development stages from conception in the laboratories through pivotal (but very expensive) Phase III trials to final regulatory approval and industrial production.

The idea of such a Fund was presented at the World Economic Forum in Davos in 2017. Several funders including the Bill and Melinda Gates Foundation, the Wellcome Trust, and the governments of India and Norway agreed to form the Coalition for Epidemic Preparedness and Innovation (CEPI). CEPI funds multiple promising candidate vaccines (using various platform technologies) against priority pathogens that pose pandemic threats, like Lassa Fever, Middle East Respiratory Syndrome (MERS), Nipah, Rift Valley fever, and Chikungunya. Thus, it is important to harmonize safety definitions among clinical trials to accurately capture the risks of adverse events of special interest (AESI) following vaccination. Fortuitously, Dr. Nadia Tornieporth, one of the early consultants to CEPI's Clinical Development team, was familiar with the Brighton Collaboration. Two of her students had done a project to assess the Performance Indicators of the Brighton Collaboration Case Definition 'Neonatal Infections' with Jan Bonhoeffer, the lead for Brighton Collaboration 1.0. I had the pleasure of meeting the students when they presented their poster at the 34th International Conference of Pharmacoepidemiology in Prague, Czech Republic in August 2018.

As Jan was ready to move on to his next passion at this time, he passed the Brighton Collaboration baton onto me, including the finalization of the SPEAC project with our CEPI project officer Nadia, officially launched in May, 2019. As shown in the Figure below, the SPEAC 1.0 project had five Work Packages (WP), described in greater detail here. Fortuitously, SPEAC 1.0 had several months to develop its standard modus operandi (which included global experts working remotely) by the time the COVID-19 pandemic hit in 2020. For the following two years, SPEAC with others in the vaccine safety community faced immense workload as multiple COVID-19 vaccines were introduced and several AESI's like thrombosis with thrombocytopenia syndrome (TTS) and myocarditis were detected. Based on the lessons learned from the pandemic, the SPEAC team worked with our new CEPI project

officer Dr. Rebecca Chandler to develop SPEAC 2.0. This expanded project will help CEPI 2.0's mission to further shorten the development time for a candidate vaccine against a new Disease X to 100 days (from 300 days for COVID-19). In addition to continuation of the five SPEAC 1.0 WPs, SPEAC 2.0 has three new WPs (see Figure): WP4-6, focusing on Digital Transformation, Special Populations, and Active Surveillance, described in greater detail here. I look forward to providing information about our progress in future VSQ's.

Figure:



Sincerely,

Robert (Bob) T. Chen
Scientific Director
Brighton Collaboration

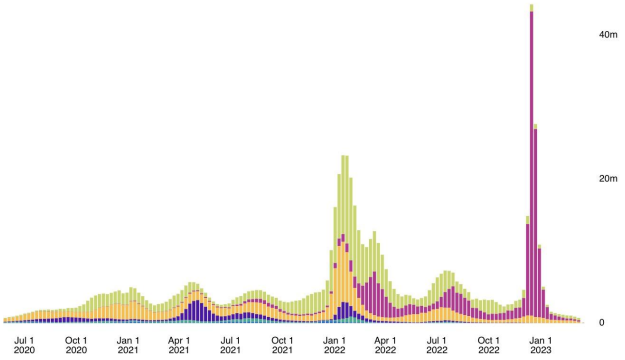
GLOBAL OUTBREAKS

COVID-19

Quick Links

- COVID-19 Dashboard (Johns Hopkins University) has stopped active data collection
- COVID-19 Vaccine Tracker and Landscape (WHO)
- Coronavirus Drug and Treatment Tracker (NYT)
- Clinical Management of COVID in Adults (NIH)
- Brighton Collaboration: Key Resources for COVID-19 Vaccine Safety Analyses
- Tracking Omicron and Other Coronavirus Variants (CDC)

Omicron and Other Coronavirus Variants



Weekly global trends in COVID-19 cases (click to see full-size graphic).

Control Measures in Flux Across the Globe

The Omicron sub-variants continue to cause most Covid-19 cases, and surveillance is ongoing for emergence of novel variants that evade vaccine-induced immunity. XBB 1.5 has spread rapidly and now accounts for most of the new cases in the US. This latest variant may be more communicable. As of October 1 the WHO decided these new variants do not rise to a cause of concern. Bill Gates comments on what needs to be done to prepare for the next epidemic, including global collaboration and financial support from wealthy countries. The NIH is piloting a program to facilitate diagnosis and treatment using telemedicine. In response to nationwide protests, China has relaxed the Covid prevention mandates that comprise its "Zero COVID" policy. The effects on Covid transmission and caseload are to be determined, as the sudden opening of the country causes concern among many.

A rapid Covid-19 test that can identify Covid-19 and 2 strains of influenza is now approved in principle but its exact composition is still being discussed.

(Very) Long Covid

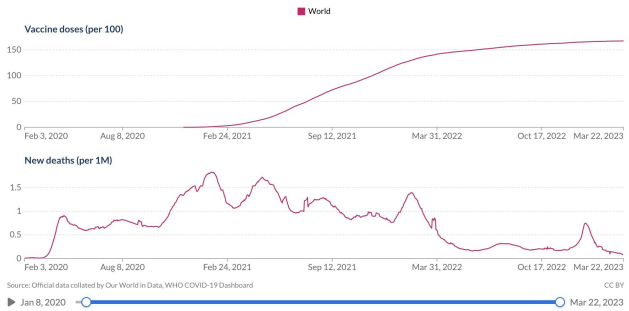
After the pandemic subsides, we may still be dealing with adverse health effects among individuals who recovered from acute infections. Long Covid continues to affect some individuals long after the virus has been cleared, with up to 200 symptoms lasting a year or more being reported. So-called "very long Covid", with symptoms persisting up to 18 months post-infection, is described in over 100 patients from a hospital in Italy.

Vaccine Safety

Brighton Collaboration has been involved along with the Coalition for Epidemic Preparedness Innovations (CEPI) in developing a 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 AESI's are available here.

New studies describe vaccine adverse event profiles in pregnant women. An increase in rhythm abnormalities, inflammation, myocardial infarction, and heart failure one year after the acute phase of Covid-19 continue to be reported, though outcomes associated with vaccine-associated myocarditis are less severe than those associated with Covid-associated myocarditis. Chronic urticaria after Covid-19 vaccination is newly reported in Switzerland.

Vaccine Effectiveness



Covid-19 vaccine doses and confirmed deaths (click to see full-size graphic)

A cost analysis in New York City showed that every dollar spent now on vaccination saves $10 later.

Vaccine Intentions & Hesitancy

Parental hesitancy to vaccinate children persists in the US, despite final full FDA approval of Covid vaccination for children as young as 6 months. Parents' decision to have children vaccinated parallels their acceptance of vaccines for themselves according to the study, "Parental Factors Affecting Decision to Vaccinate Their Daughters."

Vaccine hesitancy can be influenced by social, political, economic, and geographic factors, as evidenced by a study of Covid vaccine intentions in different language areas of Belgium and among migrant groups in Europe. Covid-19 vaccine concerns appear to be carrying over to use of traditional childhood vaccines. Opposition to school vaccine mandates has grown since 2019.

Combating Covid vaccine hesitancy requires effective communication of the benefits and risks of vaccination, and should be tailored to specific audiences depending on the type and amount of information they want. Meta-summaries of Covid vaccine evidence could be an effective communication and education method.

Novel approaches, such as improvisational theater, can build provider skills and confidence to have discussions about vaccine safety with hesitant patients. Waiting room reminders are also helpful Effect of covid-19 messaging platforms .

The WHO's "Vaccine safety and false contraindications to vaccines" manual is another helpful tool to understand common misconceptions about vaccination.

More generally exists the need to maintain confidence in conventional medicine: Building patient trust to support medication adherence. It is known that as many as 50% of prescriptions are never filled for a variety of reasons, among them cost.

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MPOX

Over 80,000 cases of Mpox, formerly known as monkeypox, have been reported in over 100 countries since May 2022. Smallpox vaccine is effective against Mpox infection, but limited amounts of vaccine are available. There is no known plan to increase supply; however, the FDA has authorized intradermal vaccine administration which uses smaller doses of the vaccine and effectively increases vaccine availability.

RESPIRATORY SYNCYTIAL VIRUS

Respiratory syncytial virus (RSV) has added a third major concern to the winter respiratory virus scene in the US. The "tripledemic" of Covid, seasonal influenza, and RSV threaten hospital surges and emphasize the necessity of Covid and flu vaccination, especially in children. While no vaccine is currently authorized for RSV prevention, vaccine candidates for older adults and for pregnant people have shown promising safety and efficacy profiles in clinical trials. On February 28, the FDA's Vaccines and Related Biological Products Advisory Committee narrowly voted to recommend Pfizer's RSV vaccine candidate for older adults, followed by a vote to recommend GSK's RSV vaccine candidate the following day. These could be the first FDA-approved RSV vaccines in the world, paving the way for pediatric RSV vaccines.

Political Vaccinology

Two Idaho lawmakers introduce legislation to criminalize giving out mRNA vaccines

Physicians object to court ordered ivermectin for Covid-19

Congress poised to repeal Covid vaccine mandate for troops in military bill..

History

In an Henrik Ibsen play from 1882, a physician in a resort discovers the cause of local illnesses: contaminated water. But because he refuses to hide this information, which would ruin the resort business, the physician is called "An Enemy of the People."

BC MEMBER NEWS & ANNOUNCEMENTS

CEPI-SPEAC Press Release

In its press release on 20 December 2022, CEPI announced that it is renewing and expanding its partnership with the Brighton Collaboration via the Safety Platform for Emergency VACcines (SPEAC) for four more years.

> "The team played a key role during the development and roll-out of COVID-19 vaccines through the Brighton Collaboration's efforts to create harmonized guidelines for collection of data on potential side effects."

On the role the Brighton Collaboration plays in CEPI-SPEAC's efforts on the safety of future vaccines to prevent and respond to pandemics, Dr Melanie Saville, Executive Director of R&D at CEPI, shared the following:

> "Careful safety evaluation is paramount in vaccine development, so access to the Brighton Collaboration's outstanding vaccine safety expertise is crucial to the success of CEPI's vaccine portfolio. SPEAC's expanded scope will be vital to ensuring the safety of CEPI-funded vaccines and platforms over the next 5 years."

Digital Innovations in Vaccine Safety (DIVaS) Working Group

The Brighton website is undergoing renovation and we need help from frequent users to advance requirements and provide design feedback. To do this, we are reactivating DIVaS and have begun to accept CV's from those who are interested in being a part of it. If you are interested in joining the DIVaS WG, please email your CV to bc-coordinator@taskforce.org.

The scope of the web redesign will include:

1. Improved navigation for all Brighton tools and services
2. Interoperability with the new SPEAC website as it gets designed and launched in Q1 2023
3. Improved collaboration tools
4. Updated content with improved meta data tagging and associated search
5. Resource section providing access to short videos and help content to advance understanding and adoption of Brighton work

6. Improved community building and engagement tools/services

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 session will be planned for July 2023. To receive the virtual journal club link and to receive journal club announcements, please join the mailing list by completing this Google Form.

New Brighton Collaboration Publications

In the recently launched website, newly published Brighton Collaboration articles and tools will be posted in English and some in Chinese, Spanish, French, or Portuguese.

A couple of notable recent publications are:

- Sensorineural Hearing Loss: AESI Case Definition Companion Guide
- Anosmia Case Definition
- Preterm Birth and Assessment of Gestational Age: Case Definition Companion Guide
- Vaccines based on the replication-deficient simian adenoviral vector ChAdOx1: Standardized template with key considerations for a risk/benefit assessment
- Thrombosis/Thromboembolism Case Definition
- Vaccine-associated enhanced disease (VAED): Case Definition Companion Guide
- Anaphylaxis V2 Case Definition
- Thrombosis and Thromboembolism: Case Definition Companion Guide
- Myocarditis and Pericarditis: Case Definition Companion Guide

Caveat Emptor

There are about 300,000 articles coded Covid-19 in PubMed. Unfortunately, a review found that 138 articles have been withdrawn but some continue to be cited. Withdrawal of articles has increased in recent years.

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 to bc-coordinator@taskforce.org, 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.

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LITERATURE

There are about 2,400 citations per year in PubMed coded Vaccine Safety. This is increasing by about 200 per month. Here are a few which may be of interest:

1. **A new type of vaccine for a new purpose. Multi-antigen spherical nucleic acid cancer vaccines.** Teplensky, Michelle H., Evangelopoulos Michael, Dittmar Jasper W., Forsyth Connor M., Sinegra, Andrew J., Wang, Shuya, Mirkin, Chad A. Nature Biomedical Engineering. 2023; DOI: 10.1038/s41551-022-01000-2

Abstract: Cancer vaccines must activate multiple immune cell types to be effective against aggressive tumours. Here we report the impact of the structural presentation of two antigenic peptides on immune responses at the transcriptomic, cellular and organismal levels. We used spherical nucleic acid (SNA) nanoparticles to investigate how the spatial distribution and placement of two antigen classes affect antigen processing, cytokine production and the induction of memory. Compared with single-antigen SNAs, a single dual-antigen SNA elicited a 30% increase in antigen-specific T cell activation and a two-fold increase in T cell proliferation. Antigen placement within dual-antigen SNAs altered the gene expression of T cells and tumour growth. Specifically, dual-antigen SNAs encapsulating antigens targeting helper T cells and with externally conjugated antigens targeting cytotoxic T cells elevated antitumour genetic pathways, stalling lymphoma tumours in mice. Additionally, when combined with the checkpoint inhibitor anti-programmed-cell-death protein-1 in a mouse model of melanoma, a specific antigen arrangement within dual-antigen SNAs suppressed tumour growth and increased the levels of circulating memory T cells. The structural design of multi-antigen vaccines substantially impacts their efficacy.

2. **GBS again. Reports of Guillain-Barré Syndrome After COVID-19 Vaccination in the United States.** Abara WE, Gee J, Marquez P, et al. JAMA Netw Open. 2023;6(2):e2253845. doi:10.1001/jamanetworkopen.2022.53845

Abstract: Because of historical associations between vaccines and Guillain-Barré syndrome (GBS), the condition was a prespecified adverse event of special interest for COVID-19 vaccine monitoring.

Objective: To evaluate GBS reports to the Vaccine Adverse Event Reporting System (VAERS) and compare reporting patterns within 21 and 42 days after vaccination with Ad26.COV2.S (Janssen), BNT162b2 (Pfizer-BioNTech), and mRNA-1273 (Moderna) COVID-19 vaccines.

Design, Setting, and Participants: This retrospective cohort study was conducted using US VAERS reports submitted during December 2020 to January 2022. GBS case reports verified as meeting the Brighton Collaboration case definition for GBS in US adults after COVID-19 vaccination were included.

Exposures: Receipt of the Ad26.COV2.S, BNT162b2, or mRNA-1273 COVID-19 vaccine.

Main Outcomes and Measures: Descriptive analyses of GBS case were conducted. GBS reporting rates

within 21 and 42 days after Ad26.COV2.S, BNT162b2, or mRNA-1273 vaccination based on doses administered were calculated. Reporting rate ratios (RRRs) after receipt of Ad26.COV2.S vs BNT162b2 or mRNA-1273 within 21- and 42-day postvaccination intervals were calculated. Observed-to-expected (OE) ratios were estimated using published GBS background rates.

Results: Among 487 651 785 COVID-19 vaccine doses, 17 944 515 doses (3.7%) were Ad26.COV2.S, 266 859 784 doses (54.7%) were BNT162b2, and 202 847 486 doses (41.6%) were mRNA-1273. Of 295 verified reports of individuals with GBS identified after COVID-19 vaccination (12 Asian [4.1%], 18 Black [6.1%], and 193 White [65.4%]; 17 Hispanic [5.8%]; 169 males [57.3%]; median [IQR] age, 59.0 [46.0-68.0] years), 275 reports (93.2%) documented hospitalization. There were 209 and 253 reports of GBS that occurred within 21 days and 42 days of vaccination, respectively. Within 21 days of vaccination, GBS reporting rates per 1 000 000 doses were 3.29 for Ad26.COV.2, 0.29 for BNT162b2, and 0.35 for mRNA-1273 administered; within 42 days of vaccination, they were 4.07 for Ad26.COV.2, 0.34 for BNT162b2, and 0.44 for mRNA-1273. GBS was more frequently reported within 21 days after Ad26.COV2.S than after BNT162b2 (RRR = 11.40; 95% CI, 8.11-15.99) or mRNA-1273 (RRR = 9.26; 95% CI, 6.57-13.07) vaccination; similar findings were observed within 42 days after vaccination (BNT162b2: RRR = 12.06; 95% CI, 8.86-16.43; mRNA-1273: RRR = 9.27; 95% CI, 6.80-12.63). OE ratios were 3.79 (95% CI, 2.88-4.88) for 21-day and 2.34 (95% CI, 1.83-2.94) for 42-day intervals after Ad26.COV2.S vaccination and less than 1 (not significant) after BNT162b2 and mRNA-1273 vaccination within both postvaccination periods.

Conclusions and Relevance: This study found disproportionate reporting and imbalances after Ad26.COV2.S vaccination, suggesting that Ad26.COV2.S vaccination was associated with increased risk for GBS. No associations between mRNA COVID-19 vaccines and risk of GBS were observed.

3. **Vaccine-associated hypersensitivity.** McNeil, M. M., & DeStefano, F. (2018). The Journal of Allergy and Clinical Immunology, 141(2), 463–472.

Abstract: Vaccine-associated hypersensitivity reactions are not infrequent; however, serious acute-onset, presumably IgE-mediated or IgG and complement-mediated anaphylactic or serious delayed-onset T cell-mediated systemic reactions are considered extremely rare. Hypersensitivity can occur because of either the active vaccine component (antigen) or one of the other components. Postvaccination acute-onset hypersensitivity reactions include self-limited localized adverse events and, rarely, systemic reactions ranging from urticaria/angioedema to full-blown anaphylaxis with multisystem involvement. Risk of anaphylaxis after all vaccines is estimated to be 1.31 (95% CI, 0.90-1.84) per million vaccine doses, respectively. Serious hypersensitivity reactions after influenza vaccines are particularly important because of the large number of persons vaccinated annually. Influenza vaccines are unique in requiring annual changes in the vaccines' antigenic composition to match the predicted circulating influenza strains. Recently, novel influenza vaccine types were introduced in the United States (recombinant vaccines, some with higher antigen

content and a new adjuvanted vaccine). Providers should be aware of changing recommendations on the basis of recent published evidence for persons with a history of egg allergy to receive annual influenza vaccination. Further research is needed to elucidate the pathophysiology and risk factors for reported vaccine-associated adverse events. Further research is also needed to determine whether repeated annual inactivated influenza vaccination, the number of vaccine antigens administered at the same time, and the current timing of routine infant vaccinations are optimal for overall population well-being

4. **What people are saying on social media. COVID-19 Vaccine-Related Discussion on Twitter: Topic Modeling and Sentiment Analysis**. Lyu JC, Han EL, Luli GK. J Med Internet Res. 2021 Jun 29;23(6):e24435. doi: 10.2196/24435.

Background: Vaccination is a cornerstone of the prevention of communicable infectious diseases; however, vaccines have traditionally met with public fear and hesitancy, and COVID-19 vaccines are no exception. Social media use has been demonstrated to play a role in the low acceptance of vaccines.

Objective: The aim of this study is to identify the topics and sentiments in the public COVID-19 vaccine-related discussion on social media and discern the salient changes in topics and sentiments over time to better understand the public perceptions, concerns, and emotions that may influence the achievement of herd immunity goals.

Methods: Tweets were downloaded from a large-scale COVID-19 Twitter chatter data set from March 11, 2020, the day the World Health Organization declared COVID-19 a pandemic, to January 31, 2021. We used R software to clean the tweets and retain tweets that contained the keywords vaccination, vaccinations, vaccine, vaccines, immunization, vaccinate, and vaccinated. The final data set included in the analysis consisted of 1,499,421 unique tweets from 583,499 different users. We used R to perform latent Dirichlet allocation for topic modeling as well as sentiment and emotion analysis using the National Research Council of Canada Emotion Lexicon.

Results: Topic modeling of tweets related to COVID-19 vaccines yielded 16 topics, which were grouped into 5 overarching themes. Opinions about vaccination (227,840/1,499,421 tweets, 15.2%) was the most tweeted topic and remained a highly discussed topic during the majority of the period of our examination. Vaccine progress around the world became the most discussed topic around August 11, 2020, when Russia approved the world's first COVID-19 vaccine. With the advancement of vaccine administration, the topic of instruction on getting vaccines gradually became more salient and became the most discussed topic after the first week of January 2021. Weekly mean sentiment scores showed that despite fluctuations, the sentiment was increasingly positive in general. Emotion analysis further showed that trust was the most predominant emotion, followed by anticipation, fear, sadness, etc. The trust emotion reached its peak on November 9, 2020, when Pfizer announced that its vaccine is 90% effective.

Conclusions: Public COVID-19 vaccine-related discussion on Twitter was largely driven by major events about COVID-19 vaccines and mirrored the active news topics in mainstream media. The discussion also demonstrated a global perspective. The increasingly positive sentiment around COVID-19

vaccines and the dominant emotion of trust shown in the social media discussion may imply higher acceptance of COVID-19 vaccines compared with previous vaccines.

5. **AEs in a high risk group. Adverse events following the first, second and third doses of a COVID-19 vaccine in hemodialysis patients.** Pai MF, Tung KT, Hsu SP, Peng YS, Lin WY, Yang JY, Wu HY, Chiu YL, Shu KH, Tsai WC. Ren Fail. 2023 Dec;45(1):2172432. doi: 10.1080/0886022X.2023.2172432. PMID: 36715434

Background: This study aimed to identify adverse events following the first three doses of COVID-19 vaccines in hemodialysis (HD) patients. Risk factors associated with postvaccination adverse events were explored.

Methods: Postvaccination adverse events in 438 HD patients who received 3 doses of COVID-19 vaccines were prospectively assessed. The adverse events among three doses were compared using generalized linear mixed models. Factors associated with adverse events were assessed with multivariate analyses.

Results: The vast majority of participants received Oxford/AstraZeneca ChAdOx1 as their first two doses and Moderna mRNA-1273 as their third dose. Overall, 79%, 50% and 84% of the participants experienced at least one adverse event after their first, second, and third doses, respectively. These adverse events were mostly minor, short-lived and less than 5% reported daily activities being affected. Compared with the first dose, the second dose caused a lower rate of adverse events. Compared with the first dose, the third dose elicited a higher rate of injection site reactions and a lower rate of systemic reactions. Multivariate analyses showed that every 10-year increase of age (odds ratio 0.67, 95% confidence intervals 0.57-0.79) was associated with decreased risk of adverse events, while female sex (2.82, 1.90-4.18) and arteriovenous fistula (1.73, 1.05-2.84) were associated with increased risk of adverse events. Compared with Oxford/AstraZeneca ChAdOx1, Moderna mRNA-1273 was associated with an increased risk of injection site reactions.

Conclusions: COVID-19 vaccination was well tolerated in HD patients. Age, sex, dialysis vascular access and vaccine types were associated with post-vaccination adverse events.

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Brighton Collaboration Science Board

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