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Brighton Collaboration 2.0

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Update on COVID-19 vaccine safety monitoring

Vaccine safety monitoring requires broad and timely collaboration between national, regional and global stakeholders.[1]

The role of vaccine safety surveillance during COVID-19 vaccine introduction is to facilitate the early detection, investigation and analysis of adverse events following immunization (AEFIs) and adverse events of special interest (AESIs) to ensure an appropriate and rapid response.[2]

Since our last update, stakeholders from around the globe have continued to monitor the safety of COVID-19 vaccines. Guillain-Barré syndrome and kidney injury have been identified as potential vaccine safety signals. Plausible causal relationships between mRNA vaccination and the onset of myocarditis or pericarditis and AstraZeneca or Janssen vaccination and the onset of thrombosis with thrombocytopenia syndrome have been confirmed by the WHO Global Advisory Committee on Vaccine Safety (GACVS) COVID-19 subcommittee.

Guillain-Barré syndrome (GBS)

The GACVS COVID-19 subcommittee reviewed VigiBase data and individual case safety reports of the onset of GBS following receipt of the AstraZeneca or Janssen/Johnson & Johnson COVID-19 vaccines. The subcommittee also considered statements from the EMA and U.S. Food and Drug Administration (FDA) following reviews of GBS cases reported post-vaccination. They recommend more rigorous studies, including comparison of cases in vaccinated and unvaccinated populations, health professional monitoring and reporting of AEFI, active safety surveillance for cases of post-vaccination GBS where possible, and vaccine recipients have full knowledge of GBS signs and symptoms and are encouraged to seek medical attention if any occur.

Links to the Brighton Collaboration Guillain-Barré and Miller Fisher Syndromes case definitions and guidelines and companion guide.

Kidney injury

On August 11, the European Medicines Agency (EMA) advised they are assessing case reports of glomerulonephritis and nephrotic syndrome onset following receipt of the Pfizer-BioNTech or Moderna mRNA COVID-19 vaccines. A subsequent literature view by this author identified eight reports and 20 letters to the editor (36 cases) and one editorial published regarding acute kidney injury following COVID-19 vaccination from May to August 2021 in various peer reviewed journals related to nephrology.

The reports and letters presented cases of de novo or relapse of minimal change disease, IgA nephropathy, anti-neutrophil cytoplasmic antibody-associated vasculitis, anti-glomerular basement membrane glomerulonephritis, membranous glomerulonephropathy, IgG4-related disease and lupus nephritis. The reported cases onset following receipt of the first or second AstraZeneca (2), Janssen

[1] WHO. Covid-19 vaccines: safety surveillance manual [Internet]. Geneva: World Health Organization; 2020. Available from: https://apps.who.int/iris/handle/10665/338400. page 17

[2] Ibid. page 39

(1), Pfizer-BioNTech (18), Moderna (14), or Sinovac (1) vaccination. The EMA review findings are much anticipated.

Myocarditis or pericarditis

The GACVS COVID-19 subcommittee considers that a causal relationship between receipt of a Pfizer-BioNTech or Moderna mRNA COVID-19 vaccines and the very rare onset of myocarditis/pericarditis is plausible. Post-mRNA COVID-19 vaccination myocarditis is more likely to present in young males aged under 40 years with four days of their second vaccination. This does not exclude presentation in females, other age groups, or after the first vaccination. Post-mRNA vaccination pericarditis is more likely to present in adults aged 40 years or older, around 20 days after the first or the second vaccination. Klein (2021) reported an increase in the risk of myocarditis or pericarditis of 8–9 cases per one million doses of vaccine in individuals aged 12–39 years within seven days of their first or second vaccination. Across all ages, Barda et al. (2021) estimated up to an additional three cases of myocarditis for every 100,000 vaccinations, and one additional case of pericarditis for every 100,000 vaccinations.

Link to the Brighton Collaboration myocarditis and pericarditis interim case definitions (comments and suggestions on the developing documents are welcome).

Thrombosis with thrombocytopenia syndrome (TTS)

The GACVS COVID-19 subcommittee considers that a causal relationship between receipt of the AstraZeneca or Janssen/Johnson & Johnson COVID-19 vaccines and onset of TTS is plausible. The incidence of TTS reported by Park (2021) for the Janssen vaccine was 1:312,000 vaccinations (U.S.), and for the AstraZeneca vaccine 1:69,800 vaccinations (U.K.), 1:55,000 vaccinations (Canada), and 1:26,500 vaccinations (Norway). TTS is more likely to be seen in females aged under 50–60 years, within 5–28 days after the first vaccination.

Link to the Brighton Collaboration thrombosis with thrombocytopenia syndrome interim case definition.

The benefits of COVID-19 vaccination in the prevention of hospitalization, intensive care unit admission, and long-term disability or death outweigh the potential harms associated with vaccination (U.S. Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, 2021).

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COVID-19

Over 170,000 citations coded COVID-19 are listed in PubMed. Many appear to be from China but from many other countries as well. This is a remarkable achievement in one year. The signs, symptoms, course, and sequelae of this disease are still evolving and probably will continue to do so for some time. One estimate is that 25% of COVID-19 papers are appearing on the preprint servers. Presumably much of this work will appear in print journals. There are also numerous webinars sponsored by the AMA and other organizations. One issue of the Journal of American Medical Association had six articles on COVID-19 and dermatology, cardiology, etc. For non-specialists, Carlos del Rio has 15 articles summarizing some parts of the COVID-19 story. His latest article discusses many important unknowns such as the duration of antibodies. Johns Hopkins University maintains a COVID-19 dashboard which provides a daily global update for 30 countries. A recent paper attempts to describe COVID-19 as a multisystem disease.

In terms of pathophysiology, the virus first binds ACE ll (angiotensin converting enzyme) receptors in the nasopharynx. This receptor is present in many organs including the endothelium. It can cause total destruction of the lung but actually affects multiple organ systems. Over 130 patients have received a lung transplant, many double. Assessment of the frequency and variety of persistent symptoms include fatigue and somnolence, which affect about ⅓ of survivors, so-called “long haulers”. The Virginia health department has prepared a chart of frequent long term effects Long term effects of covid 19 Virginia dept. Frequent cardiac effects have been reported and coagulopathy has been reported. For the generalist, an article on pathophysiology, transmission, diagnosis and treatment was recently published. A chronology of disease has been proposed. A review of autopsy findings is also available.

A “new AE” COVID-19 related inflammatory multisystem disorder has been reported and is similar to Kawasaki disease. Its status is currently being discussed.

Delta, a double mutant originally found in India, has spread widely worldwide and now accounts for 90% of new infections in the US. Delta is more transmissible than the wild type. As a result, there is a new surge in infections and hospitalizations. About 90% of hospitalized patients are unvaccinated. Breakthrough infections are also reported but these cases are usually milder. An initial summary of breakthrough cases has recently appeared. Initial results say that the current vaccines will give effective protection against these mutants except perhaps the South African. Autoantibodies have been found in some cases and it has been proposed that they could account for some long term symptoms. COVID-19 antibodies have been found in breastmilk. On a molecular basis, it has been found that individuals produce a variety of antibodies to COVID-19, some more potent than others. With this information about “Super Antibodies”, there is an attempt to reverse engineer a vaccine. A new variant, mu, is attracting attention.

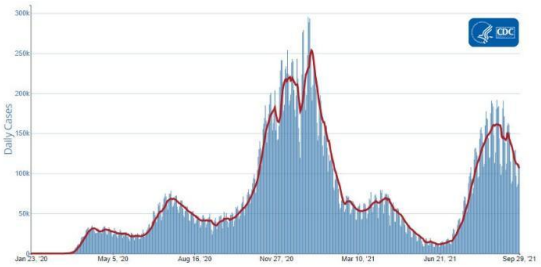
WHO has issued a first report of the world's overall response to COVID-19. This report documents failures at every turn. And the U.S. Congress shows, unintentionally, masks work.

The New York Times continues to publish COVID-19 case counts as well as vaccine administration efforts in the US. There are also detailed diagrams of the COVID-19 genome and variant tracker.

Daily Trends in Number of COVID-19 Cases in the United States Reported to CDC

Treatment

Remdesivir has been approved for use in certain cases; however, its effect appears to be modest.



bamlanivimab, a monoclonal antibody that blocks attachment of the virus to the ACE2 receptor, received emergency approval. To date, progress toward effective therapy has been disappointing. A recent publication describes how COVID-19 infection affects host cell processes. This should lead to antiviral drugs. A federal budget includes several million dollars for research on COVID-19 treatment. Articles attesting to the lack of efficacy of hydroxychloroquine continue to appear. The NYTimes maintains a report on progress in drug development. Merck has just announced a promising antiviral drug. The FDA has to announce a dedicated reporting system for Covid-19 therapeutics. The Regeneron product, bamlanivimab, received emergency FDA approval and is being used. It is a unique double antibody drug which acts by attaching to COVID-19 virus particles and thereby reducing viral load. Lilly has a similar product.

Continuing this approach, a group of protein chemists is trying to develop molecules that would be even more efficacious. Another novel idea which has appeared is a bifunctional compound used as nasal spray which would prevent viruses from attaching to the ACE2 receptor. A trial of convalescent serum in the emergency room was halted recently for lack of efficacy.

COVID-19 vaccine

Moderna and Pfizer-BioNTech (PB) vaccines are used extensively in the US, with about 300M total doses to date. Daily doses have fallen greatly to 1M. Municipalities have tried various ideas to encourage vaccination such as mobile immunization sites and even lotteries. Mandates appear to be effective. The numbers vary greatly by age, state, political party, and religion. The vaccines are now approved for ages 12 and up. Real world data agree with the first trial data as to efficacy in the 90% range. A negative is that the PB requires extreme cold for storage and transport. They both use a novel messenger RNA (mRNA) platform. A third vaccine, Johnson and Johnson/Janssen has recently been approved and is already being used and reported 70-90% success. This vaccine uses a viral vector platform and has advantages in stability and cost and only requires one dose. Use of this vaccine is slowed because of serious problems at one manufacturing facility. Because of the mutants that have appeared, 2nd generation vaccines are already in progress. One goal is to develop a vaccine with broader efficacy. The FDA has announced that 2nd generation vaccines will not require the usual large trials. Instead, it may be possible to follow some immunological markers in a few hundred people for example. Actually, about 13 vaccines are currently on the world market. This includes vaccines from Russia, China, and India. A Cuban vaccine is in an advanced stage of development. The New York Times maintains a list of the status of the 70 odd vaccines in development. About 6 different platforms are being tried. This variety of vaccines being used in many countries makes data interpretation difficult and requires the utmost attention to detail. Even two vaccines that might be thought to be identical, Moderna and PB may have subtle differences and some different effects. There may be other changes in vaccine trials in the future because of experiences during this pandemic. The history of the development of mRNA vaccines is beginning to appear in the popular press. One woman, Kati Kariko, persistently pursued for 10 years her belief that this idea could work. She has recently received the Kovik and other prizes . Of course there are other possible applications of this approach such as in long pursued gene therapy. Moderna reportedly has about 25 products in advanced stages of development. A detailed graphic outline of the production process has also appeared.

Since supplies of vaccines are still limited worldwide, discussions continue concerning the priority of distribution. Furthermore, more worldwide distribution is being addressed by the COVAX program, COVAX cuts its 2012 forecast. Allergic reactions have appeared as an AE concern since mass vaccinations began. Most individuals were female and had a history of severe allergic reactions. A recent publication reports 66 known anaphylactic reaction cases involving both vaccines and compares them. The NIH has launched a study to determine if people

with a history of allergy or a mast cell disorder are at higher risk of systemic allergic reactions to the mRNA vaccines. Other possible vaccine-related AEs continue to be mentioned and are on the lookout such as thrombosis with thrombocytopenia syndrome (TTS), myocarditis and facial-paralysis and Guillain Barré syndrome. A report of the most reported AEs after each mRNA vaccine and each dose is generally consistent with the clinical trial results. The authors point out that although local and systemic AEs are expected and often transient, they may have the most immediate effect on patients' perception of the vaccination experience. Therefore, setting a patient's expectations may alleviate some anxiety elicited by post-vaccination

TTS is reported after the AstraZeneca (AZ) and Johnson and Johnson/Jansen (JJJ) vaccines. The original review found about 30 cases of TTS after 5M doses of vaccine. About 1200 cases of myocarditis have been reported after the mRNA-based vaccines. Most cases are in young men and are relatively mild. A CDC committee has concluded that there is a possible association with the vaccines. In both cases the benefit of the vaccine far exceeds the risk, but intense surveillance should continue. The Brighton Collaboration has prepared case-finding definitions of TTP and myocarditis. The definitions are available on the Brighton website.

Brighton Collaboration has been involved along with CEPI in developing a list of possible AEFIs that may be associated with a COVID-19 vaccine. One concern is the potential for enhanced disease. This is theoretical for COVID-19 but has been seen with SARS and MERS-CoV vaccines in animal models.

COVID-19 testing

With little public notice there have been a series of improvements in virus testing. Now there's even a test that can be used at home. While speed usually compromises accuracy, each has its advantages. Now these tests must be evaluated as to how they perform with the Covid-19 mutant. A combined Covid-19 influenza test has recently become available.

COVID-19 Vaccine Data Resources

Brighton Collaboration has assembled a COVID-19 vaccine safety resource. Topics include regulatory approvals, risk management plans, usage recommendations, adverse events and databases. This resource is intended for public use by anyone who is interested in COVID-19 vaccine details. Comments and additional sources may be sent to varricchio@comcast.net.

In general, CDC and MMWR are good sources. The CDC/FDA's Vaccine AE Reporting System (VAERS) database is available to the public. The AMA also maintains a resource of Covid-19 articles, webinars, interviews etc.

VACCINE HESITANCY

Discussion continues concerning how to deal with vaccine misinformation and increase public confidence. The CDC has a 1 page "tip sheet" on frequent vaccine questions and responses. These are available in bulk Should physicians be encouraged to keep some in their waiting areas. Heidi Larson, a London anthropologist, proposes how to deal with false information and build trust. She studies rumors and is the founder of the Vaccine Confidence Project. Also see, "the science of changing someone's mind". Duke university medical school has added a course. The US Covid-19 relief law contains funds to work on the effort. Robert Kennedy Jr. has been a prominent vaccine doubter. His granddaughter, a physician, has publicly rebutted his position.

In recognition of the critical importance of COVID-19 vaccines and the need to understand their safety, the CONSIDER (**CO**vid-19 vacci**N**e **S**afety quest**I**ons an**D** h**E**althcare p**R**oviders) working group (WG) was created in September 2020. The CONSIDER WG aims to provide clear, comprehensive answers to questions pertaining to COVID-19 vaccine safety prior to, and during the vaccines roll out to 1) facilitate scientific discussion between stakeholders, including front line

health workers with potential vaccine recipients and 2) increase comprehension and transparency of information to facilitate acceptance and uptake. As more questions come to the group's attention or more information becomes available, including on AEFI (from COVID-19 vaccine clinical trials and early experience with vaccine introduction in countries), the answers are being updated and new answers posted here and are cross-referenced on other sites, including on WHO's Vaccine Safety Network (VSN).

The UN has announced an effort to make reliable COVID-19 information available to everyone called "Verified". It enables volunteers from around the world to share information. The theory is to enable social organization, people providing information to friends, family, and social contacts. More recently WHO has announced a collaboration with Wikipedia which is known to be frequently consulted by the public for health information. The WHO will make its information available for posting. The WHO also maintains a list of credible vaccine information sources, the Vaccine Safety Network (VSN). This contains primarily government sources but Brighton has just been included.

There have been numerous articles in the press about people, even military, who say that they do not want to be among the first to get the vaccine. Apparently, this is because of a feeling that a vaccine may have been rushed to market. But about 300 million have been administered in the US with about 70% having at least one dose. Peter Marks, director of CBER-FDA, has stated that in his experience as an oncologist confidence is best achieved from a relationship with a physician. It is known that a trusted intermediary can have a powerful effect. A recent survey divides the 35% vaccine hesitators into 4 groups: wait and see, high cost of lost time from work, distrust of the system, and 14% "don't believe the threat".

China and Russia have been exporting their vaccines to other nations. But relatively little is known about these products; possibly contributing to vaccine hesitancy. The Biden administration has embarked on a new multi-million advertising campaign to promote immunization. The CDC Director, Rochelle Walensky, has commented that these days most "scientific" information passes by Twitter. Therefore, responsible sources must use Twitter too. Clearly, consistency is very important. Regrettably there has been widespread resistance to immunization among healthcare workers. Then, there are physicians who have been spreading vaccine misinformation. This has also happened in New Zealand and other countries?

Un Faux Pas

An article entitled "The Safety of Covid-19 Vaccines: We Should Rethink the Policy" appeared in the *Vaccines.* This article appeared to be written by people unfamiliar with the subject and also to be a failure of the review process. Three associate editors immediately resigned. The journal retracted the article promptly but not before it had been seen by thousands. The retraction also appears in PubMed. Helen Petousis-Harris has a detailed description of this event.

I have received 2 articles for review, which I considered very thin. I'm not sure much attention was given to my comments and the articles appeared in days. Is anyone else having a similar experience?

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 will take place quarterly during SIG meetings via Webex and will be co-hosted by SIG Chair Cathy Panozzo of Moderna TX and BC member Nadja Vielot of the University of North Carolina.

To join the discussion, please complete this Google Form and we will include you on the mailing list.

Travel

If you are in England, there is an Edward Jenner House and Museum in Berkeley, England. There is also his temple of vaccinia, a sort of lean-to.

History: *When anti-vaccine sentiment turned violent: the Montreal Vaccine Riot of 1885*

CMAJ Apr 2021, 193(14) E490-E492; doi: 10.1503/cmaj.202820.
Corresponding author: Jonathan M. Berman (Department of Basic Science, New York Institute of Technology College of Osteopathic Medicine at Arkansas State University, Jonesboro, AR, USA)

Political Epidemiology

The Era of Vaccine Diplomacy is Here (NY Times)
Two top FDA vaccine regulators resign
In Review, Top FDA Scientists Question Imminent Need for Booster Shot

In Spring VSQ was emailed to over 900 readers. An estimate from the returned reader survey shows 30% of readers are from the US followed by Canada and India. Occupations vary from clinical research to statistics to fund raising. All readers are invited to submit comments and articles to the VSQ.

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:

- *A Brighton Collaboration standardized template with key considerations for a benefit/risk assessment for a soluble glycoprotein vaccine to prevent disease caused by Nipah or Hendra viruses*
- *Applicability of the GAIA Maternal and Neonatal Outcome Case Definitions for the Evaluation of Adverse Events Following Vaccination in Pregnancy in High-income Countries.*

New Brighton 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. 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!

LITERATURE

There are about 2400 citations per year in PubMed coded Vaccine Safety. This is increasing by about 200 per month. I have selected a few which may be of general interest.

1. **Cardiovascular Adverse Events Reported from COVID-19 Vaccines: A Study Based on WHO Database**
   Int J Gen Med. 2021 Jul 27;14:3909-3927. doi: 10.2147/IJGM.S324349. eCollection 2021.
   Corresponding Author: Jaykaran Charan (All India Institute of Medical Sciences; Jodhpur, Rajasthan, India)

Background: Thirteen COVID-19 vaccines are granted emergency approval. It is crucial to monitor their adverse events post vaccination. The present study focuses on cardiovascular adverse events post-COVID-19 vaccination and aims to determine adverse events with the administered vaccine.

Results: For the cardiovascular system, 4863 adverse events (AEs) were reported from BNT162b2 Pfizer, 1222 AstraZeneca, Moderna, and other COVID-19 vaccines. Common adverse events observed with vaccines under study were tachycardia (16.41%), flushing (12.17%), hypertension (5.82%), hypotension (3.60%) and peripheral coldness (2.41%). Based on disproportionality analysis (IC025 values), acute myocardial infarction, cardiac arrest, and circulatory collapse were linked to the vaccines in the age group >75 years. Hypertension, severe hypertension, supraventricular tachycardia, sinus tachycardia, and palpitations were associated across all age groups and either gender. Amongst the investigations, abnormal ECG findings raised C-reactive protein, elevated D dimer, and troponin were reported in specific age groups or gender or all subjects.

Conclusion: Although cardiovascular events have been reported with the COVID-19 vaccines, the causality is yet to be established because such CVS AEs are also usually associated with the general public even without intervention. Hence, people should be administered these vaccines, and sustained monitoring of these AEs should be continued.

2. **A phase 1, randomized, placebo-controlled study to evaluate the safety and immunogenicity of an mRNA-based RSV prefusion F protein vaccine in healthy younger and older adults.**
   Hum Vaccin Immunother. 2021 May 4;17(5):1248-1261. doi: 10.1080/21645515.2020.1829899. Epub 2020 Oct 29. *Corresponding Author*: Lori Panther (Moderna Inc.; Cambridge, MA, USA)

Abstract: Respiratory Syncytial Virus (RSV) causes lower respiratory tract infections that can be severe and sometimes fatal. The risk for severe RSV infection is highest in infants and older adults. A safe and effective RSV vaccine for older adults represents a serious unmet medical need due to higher morbidity and mortality in this age group. In this randomized, partially double-blind, placebo-controlled, phase 1 dose-escalation study, we evaluated the safety, tolerability and immunogenicity of an investigational messenger ribonucleic acid (mRNA) vaccine encoding the RSV fusion protein (F) stabilized in the prefusion conformation. The study was conducted in healthy younger adults (ages ≥18 and ≤49 years) and healthy older adults (ages ≥60 and ≤79 years). Participants received mRNA-1777 (V171) or placebo

as a single intramuscular dose. For each dose level, three sentinel participants were administered open-label mRNA-1777 (V171). Seventy-two younger adults were randomized and administered 25, 100, or 200 µg mRNA-1777 (V171) or placebo, and 107 older adults were randomized and administered 25, 100, 200 or 300 µg mRNA-1777 (V171) or placebo. Primary objectives were safety and tolerability and secondary objectives included humoral and cell-mediated immunogenicity. All dose levels of mRNA-1777 (V171) were generally well tolerated and no serious adverse events related to the vaccine were reported. Immunization with mRNA-1777 (V171) elicited a humoral immune response as measured by increases in RSV neutralizing antibody titers, serum antibody titers to RSV prefusion F protein, D25 competing antibody titers to RSV prefusion F protein, and cell-mediated immune responses to RSvf.

3. Adverse Events Reported From COVID-19 Vaccine Trials: A Systematic Review

Indian J Clin Biochem. 2021 Mar 27;1-13. doi: 10.1007/s12291-021-00968-z. Online ahead of print.
Corresponding author: Jaykaran Charan (All India Institute of Medical Sciences; Jodhpur, Rajasthan, India)

Abstract: COVID-19 infection originated in Wuhan, China in December 2019 and crippled human health globally in no time. The public health emergency required urgent efforts to develop and test the efficacy and safety of vaccines to combat the COVID-19 pandemic. The emergency use approval has been granted to COVID-19 vaccines before the completion of conventional phases of clinical trials. However, there is no comprehensive review of safety data reported from the vaccine trials, which is critical information to inform the policies in order to improve uptake of COVID-19 vaccines and mitigate the risk aversion perceived due to the COVID-vaccine side effects. This study aims to systematically review and synthesize the evidence on the safety data from the published COVID-19 vaccine trials. This study followed PRISMA guidelines. We searched three major electronic databases (PubMed, Embase, and Google Scholar) for published studies between Dec 2019 and 2020. Eligible study designs were randomized trials and pre-and post-intervention evaluations. Descriptive findings of included studies were reported stratified by target population, setting, outcomes, and overall results. From PubMed, Embase, WHO database, and Google Scholar screened titles and abstracts, 11 studies were identified in this review. Most of the reactions reported were mild to moderate whereas a few with severe intensity. All reactions were resolved within 3-4 days. The commonly reported local adverse events were pain at the site of injection, swelling, and redness. The systemic reactions included fever, fatigue, myalgia, and headache. Some trials also reported laboratory derangements like decreased hemoglobin, increased bilirubin, altered SGOT and SGPT. None of these alterations were clinically manifested and were self-limiting. Few clinical trials reported serious adverse events, but they were unrelated to vaccination. This systematic review indicates that COVID-19 vaccines can be safe with no serious adverse events. However, long-term post-marketing surveillance data, particularly in high-risk vulnerable populations (elderly and those with co-morbidities, pregnant women, and children) is warranted to ensure the safety of COVID-19 vaccines.

4. **COVID-19 vaccine hesitancy: misinformation and perceptions of vaccine safety**
Hum Vaccin Immunother. 2021 Jul 30;1-8. doi: 10.1080/21645515.2021.1950504. Online ahead of print.
Corresponding author: Katherine Kricorian (MiOra; Encino, CA, USA)

***Abstract**:* Despite COVID-19's devastating toll, many Americans remain unwilling to receive the COVID-19 vaccine. The authors conducted a US national survey to understand the health literacy of adults regarding the vaccine, as well as their COVID-19 beliefs and experiences. People who believed the COVID-19 vaccine was unsafe were less willing to receive the vaccine, knew less about the virus and were more likely to believe COVID-19 vaccine myths. On average, they were less educated, lower income, and more rural than people who believed the vaccine is safe. The results highlight the importance of developing clear health communications accessible to individuals from varied socioeconomic and educational backgrounds.

5. **Vaccine package inserts and prescribing habits of obstetricians-gynecologists for maternal vaccination**
Hum Vaccin Immunother. 2021 Jul 8;1-10. doi: 10.1080/21645515.2021.1942714. Online ahead of print.
Corresponding author: Jannat Saini (University of Maryland; Baltimore, MD, USA)

Abstract: Despite ample evidence of the safety and efficacy of the influenza vaccine and the tetanus, diphtheria, and acellular pertussis (Tdap) vaccine during pregnancy, two-thirds of pregnant women do not receive these vaccines. Providers have a significant role in increasing prenatal vaccine uptake. It is important to understand how different sources of vaccine prescribing information, such as Food and Drug Administration package inserts, influence provider recommendations. We aimed to examine the role of vaccine package inserts in provider recommendations and perceptions of safety and effectiveness of vaccines during pregnancy. A cross-sectional survey was mailed to a random, weighted sample of American College of Obstetricians and Gynecologists Fellows living in the United States in March.

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?

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/3nPq3tE