

Serious Adverse Events of Special Interest Following mRNA COVID-19 Vaccination in Randomized Trials in Adults

By [Joseph Fraiman](#), [Juan Erviti](#), [Dr. Peter Doshi](#), and [et al.](#)

Theme: [Science and Medicine](#)

Global Research, September 07, 2022

[ScienceDirect](#) 31 August 2022

All Global Research articles can be read in 51 languages by activating the “Translate Website” drop down menu on the top banner of our home page (Desktop version).

To receive Global Research’s Daily Newsletter (selected articles), [click here](#).

Follow us on [Instagram](#) and [Twitter](#) and subscribe to our [Telegram Channel](#). Feel free to repost and share widely Global Research articles.

Abstract

Introduction

In 2020, prior to COVID-19 vaccine rollout, the Brighton Collaboration created a priority list, endorsed by the World Health Organization, of potential adverse events relevant to COVID-19 vaccines. We adapted the Brighton Collaboration list to evaluate serious adverse events of special interest observed in mRNA COVID-19 vaccine trials.

Methods

Secondary analysis of serious adverse events reported in the placebo-controlled, phase III [randomized clinical trials](#) of Pfizer and Moderna mRNA COVID-19 vaccines in adults (NCT04368728 and NCT04470427), focusing analysis on Brighton Collaboration adverse events of special interest.

Results

Pfizer and Moderna mRNA COVID-19 vaccines were associated with an excess risk of serious adverse events of special interest of 10.1 and 15.1 per 10,000 vaccinated over placebo baselines of 17.6 and 42.2 (95 % CI –0.4 to 20.6 and –3.6 to 33.8), respectively. Combined, the mRNA vaccines were associated with an excess risk of serious adverse events of special interest of 12.5 per 10,000 vaccinated (95 % CI 2.1 to 22.9); risk ratio 1.43 (95 % CI 1.07 to 1.92). The Pfizer trial exhibited a 36 % higher risk of serious adverse events in the vaccine group; risk difference 18.0 per 10,000 vaccinated (95 % CI 1.2 to 34.9); risk ratio 1.36 (95 %

CI 1.02 to 1.83). The Moderna trial exhibited a 6 % higher risk of serious adverse events in the vaccine group: risk difference 7.1 per 10,000 (95 % CI -23.2 to 37.4); risk ratio 1.06 (95 % CI 0.84 to 1.33). Combined, there was a 16 % higher risk of serious adverse events in mRNA vaccine recipients: risk difference 13.2 (95 % CI -3.2 to 29.6); risk ratio 1.16 (95 % CI 0.97 to 1.39).

Discussion

The excess risk of serious adverse events found in our study points to the need for formal harm-benefit analyses, particularly those that are stratified according to risk of serious COVID-19 outcomes. These analyses will require public release of participant level datasets.

Introduction

In March 2020, the Brighton Collaboration and the Coalition for Epidemic Preparedness Innovations partnership, Safety Platform for Emergency vACcines (SPEAC), created and subsequently updated a “priority list of potential adverse events of special interest relevant to COVID-19 vaccine trials.” [1] The list comprises adverse events of special interest (AESIs) based on the specific vaccine platform, adverse events associated with prior vaccines in general, theoretical associations based on animal models, and COVID-19 specific [immunopathogenesis](#). [1] The Brighton Collaboration is a global authority on the topic of vaccine safety and in May 2020, the World Health Organization’s Global Advisory Committee on Vaccine Safety endorsed and recommended the reporting of AESIs based on this priority list. To our knowledge, however, the list has not been applied to serious adverse events in randomized trial data.

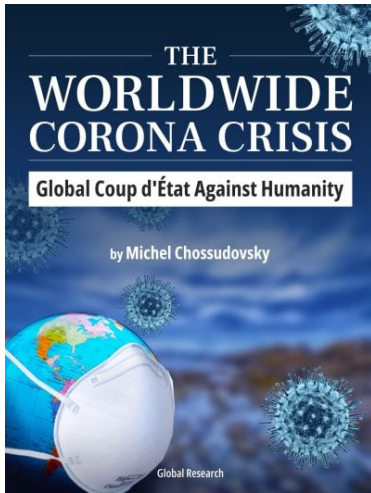
We sought to investigate the association between FDA-authorized mRNA COVID-19 vaccines and serious adverse events identified by the Brighton Collaboration, using data from the phase III randomized, placebo-controlled clinical trials on which authorization was based. We consider these trial data against findings from post-authorization observational safety data. Our study was not designed to evaluate the overall harm-benefit of vaccination programs so far. To put our safety results in context, we conducted a simple comparison of harms with benefits to illustrate the need for formal harm-benefit analyses of the vaccines that are stratified according to risk of serious COVID-19 outcomes. Our analysis is restricted to the randomized trial data, and does not consider data on post-authorization vaccination program impact. It does however show the need for public release of participant level trial datasets.

[Click here to read the full article.](#)

*

Note to readers: Please click the share buttons above or below. Follow us on Instagram and Twitter and subscribe to our Telegram Channel. Feel free to repost and share widely Global Research articles.

Featured image is from [fiercepharma](#)



The Worldwide Corona Crisis, Global Coup d'Etat Against Humanity

by Michel Chossudovsky

Michel Chossudovsky reviews in detail how this insidious project “destroys people’s lives”. He provides a comprehensive analysis of everything you need to know about the “pandemic” — from the medical dimensions to the economic and social repercussions, political underpinnings, and mental and psychological impacts.

“My objective as an author is to inform people worldwide and refute the official narrative which has been used as a justification to destabilize the economic and social fabric of entire countries, followed by the imposition of the “deadly” COVID-19 “vaccine”. This crisis affects humanity in its entirety: almost 8 billion people. We stand in solidarity with our fellow human beings and our children worldwide. Truth is a powerful instrument.”

ISBN: 978-0-9879389-3-0, Year: 2022, PDF Ebook, Pages: 164, 15 Chapters

Price: \$11.50

[Purchase directly from the Global Research Online Store](#)

You may also purchase directly at [DonorBox “Worldwide Corona Crisis” Campaign Page!](#) (NOTE: User-friendly)

The original source of this article is [ScienceDirect](#)

Copyright © [Joseph Fraiman](#), [Juan Erviti](#), [Dr. Peter Doshi](#), and [et al.](#), [ScienceDirect](#), 2022

[Comment on Global Research Articles on our Facebook page](#)

[Become a Member of Global Research](#)

Articles by: [Joseph Fraiman](#),
[Juan Erviti](#), [Dr. Peter Doshi](#),
and [et al.](#)

Disclaimer: The contents of this article are of sole responsibility of the author(s). The Centre for Research on Globalization will not be responsible for any inaccurate or incorrect statement in this article. The Centre of Research on Globalization grants permission to cross-post Global Research articles on community internet sites as long the source and copyright are acknowledged together with a hyperlink to the original Global Research article. For publication of Global Research articles in print or other forms including commercial internet sites, contact: publications@globalresearch.ca

www.globalresearch.ca contains copyrighted material the use of which has not always been specifically authorized by the copyright owner. We are making such material available to our readers under the provisions of "fair use" in an effort to advance a better understanding of political, economic and social issues. The material on this site is distributed without profit to those who have expressed a prior interest in receiving it for research and educational purposes. If you wish to use copyrighted material for purposes other than "fair use" you must request permission from the copyright owner.

For media inquiries: publications@globalresearch.ca