syndrome, have been reported to VAERS and what category of neurological side effects these have been assigned.[2]

We disagree that the beneficial effects of anti–SARS-CoV-2 vaccines outweigh the rare side effects. Every patient with a serious, disabling, or fatal side effect is one too many. Efforts should be made to make anti–SARS-CoV-2 vaccines safer.

Potential Conflicts of Interest

Nothing to report.

Data Availability

All data are available from the corresponding author.

Neurology & Neurophysiology Center, Vienna, Austria

Address correspondence to Dr Finsterer, Neurology & Neurophysiology Center, Postfach 20, Vienna 1180, Austria. E-mail: fifigs1@yahoo.de

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Reply to "VAERS Could Miss or Misinterpret Neurological Side Effects of COVID Vaccinations"

Jennifer A. Frontera, MD

We appreciate the opportunity to respond to the queries raised by the reader. Many of the points noted have already been discussed in the limitations section of the paper. Nonetheless, a few remarks require comment.

First, because the Vaccine Adverse Event Reporting System (VAERS) is an anonymized dataset, we are unable to determine the number of entries made by clinicians versus patients or families. However, based on a review of medical terminology and pronoun use in the free text, it appears that a substantial proportion of entries were made by medical professionals. We do not agree that including patient reports might cause serious adverse events to be overlooked, since such patients are likely to be hospitalized, in which case a healthcare professional is required to enter a VAERS report. Indeed, direct patient reports are more likely to represent milder symptoms that did not necessitate a healthcare visit.

Second, the reader also questioned the justification for the 42-day time frame. As mentioned in the methods section, we selected a 42-day window because this timeframe is most commonly used by the United States Centers for Disease Control and Prevention (CDC) for vaccine adverse event reporting and is considered a plausible period within which symptoms might be reasonably associated with vaccination.[1–4] Using a standardized adverse event reporting window allows our data to be compared to other datasets.

Third, with regard to symptom/syndrome coding: Our extensive manual review of over 314,000 adverse event entries by trained clinicians was a major strength of our paper and helped to mitigate against misclassifications. While we provided broad guidelines for coding, syndromes such as Guillain-Barre syndrome (GBS) or seizure, we also required the coding clinicians to apply their clinical judgement when reviewing the free text to judiciously determine ultimate classification.

Finally, we agree with the reader that, from an individual patient standpoint, any side effect may be impactful. However, from a public health standpoint, there is no disputing that the benefits of vaccination outweigh the 0.03% risk of a neurological event and the <0.0005% risk of a serious neurological event. Furthermore, the only serious neurological events that appeared to occur at a higher frequency than background rates were cerebral venous thrombosis, seizure, and GBS following the Janssen vaccination. Conversely, the rates of serious neurological events following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection were hundreds of times higher than rates following vaccination. When accounting for other acute and post-acute complications that can arise following SARS-CoV-2 infection, the benefits of vaccination outweigh the risks.

Potential Conflicts of Interest

None.

Department of Neurology, New York University Grossman School of Medicine, New York, NY, USA

Address correspondence to Dr Frontera, Department of Neurology, New York University Grossman School of Medicine, New York, NY. E-mail: jennifer.frontera@nyulangone.org

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