

Neurological side effects of COVID-19 vaccines are rare

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Letter to Editor: Response**Neurological side effects of COVID-19 vaccines are rare****Lu Lu^{1,2#}, Weixi Xiong^{1,2#}, Jie Mu^{1,2}, Qi Zhang^{1,2}, Hesheng Zhang^{1,2}, Ling Zou³, Weimin Li⁴, Li He^{1,2}, Josemir W. Sander^{1,2,5*}, Dong Zhou^{1,2*}**

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29 **Disclosures**

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31 The authors report no conflicts of interest in relation to this work.
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5 We read with interest the letter by Finsterer & Scorza on our review of potential
6 neurological effects of COVID-19 vaccines¹. Their content is not dissimilar to our
7 conclusion that post-vaccine neurological events are, at this time, relatively rare and that
8 possible long-time effects will need further prospective monitoring. It is, of course, essential
9 to remind Finsterer & Scorza that this is an evolving field, and evidence will change as
10 time goes. Therefore, pontification with the help of the retroscope is always welcomed.
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14 Some new evidence needs to be updated and clarified.
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16 The main safety concerns in the viral vector platform are blood clots reported with
17 Vaxzevria (previously COVID-19 Vaccine AstraZeneca)². By 22 March 2021, the EU drug
18 safety database reported 62 cases of cerebral venous sinus thrombosis (CVST) in people
19 who received the vaccine. This is a slight increase in the risk of this in the general
20 population³. Conversely, another study compared the incidence rate of venous
21 thromboembolic events between the Oxford–AstraZeneca vaccine population and the
22 entire Danish population before vaccination. It suggested that the reported thromboembolic
23 events do not increase⁴. The European Medicines Agency concluded that the combination
24 of blood clots and low blood platelets are extremely rare. The causality of CVST with the
25 vaccine requires further investigation. According to the Joint CDC and FDA Statement, the
26 same blood clot incidence was also associated with the Johnson & Johnson viral vector
27 vaccine, but still appears to be an extremely rare event⁵.
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33 There is also new evidence in the mRNA platform. Aside from the published phase 3
34 trials, real-world data⁶ showed a similar number of neurological events between vaccinated
35 and unvaccinated populations. Other safety results are also consistent with the extensive
36 safety and tolerability assessments conducted in Phase 1/2 and Phase 3 trials. The
37 Advisory Committee on Immunization Practices (ACIP) of the CDC also presented similar
38 data compared to the unvaccinated group. No statistical signals were detected for Bell's
39 palsy, convulsions/seizures, hemorrhagic or ischemic stroke and venous
40 thromboembolism⁷. Despite the limitation of neurological adverse events reporting, public
41 media showed a few cases of people with continuous trunk movements and limbs or
42 walking difficulties⁸. These reports were considered mainly as functional neurological
43 disorders. The causality between these symptoms and vaccination was uncertain.
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49 Based on the current evidence, though more neurological adverse effects were
50 reported with the massive worldwide vaccination, the causality is yet to be confirmed. As
51 the vaccinated population increases, inevitable more neurological incidents will be seen.
52 The link between them and the vaccine association will need to be tested by comparing their
53 incidence rate with epidemiological data preceding the pandemic. We agree that it is
54 essential to establish a transparent and efficient reporting system of vaccination safety.
55 This will require full collaboration between regulators, healthcare workers, the industry and
56 the general public.
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