Caution in Interpreting Facial Paralysis Data to Understand COVID-19 Vaccination Risks

To the Editor—Since the rollout of the COVID-19 vaccines, there have been multiple cases of postvaccination facial paralysis, raising concerns for a possible association between COVID-19 vaccines and facial paralysis. Renoud and colleagues investigated this possible association by performing a disproportionality analysis on a large pharmacovigilance database. The authors did not find any suggestion of an association, given that the rate of facial paralysis after mRNA COVID-19 vaccination was similar to rates after other viral vaccines. While we appreciate the usefulness of Bayesian drugs, and/or ADRs in the database. The authors did not find any suggestion of an disproportionality analysis on a large pharmacovigilance database. The authors did not find any suggestion of an association, given that the rate of facial paralysis after mRNA COVID-19 vaccination was similar to rates after other viral vaccines. While we appreciate the usefulness of Bayesian

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In Reply—We appreciate the concerns raised by Ng and Tan in the clinical interpretation of such pharmacoepidemiologic studies in the context of facial paralysis.

The most common cause of isolated facial paralysis is Bell palsy, the cause of which remains unclear. Numerous mechanisms for Bell palsy have been proposed, including anatomical narrowing of the facial canal, viral infection, microvascular-ischemia of the facial nerve, and immune-mediated inflammatory responses. These mechanisms may contribute to risk factors for Bell palsy, such as diabetes, hypertension, obesity, and pregnancy. Current pharmacoepidemiologic studies lack information on the detailed presenting history, medical records, comorbidities, and examination and investigation findings of the patients with facial paralysis. Thus, it is difficult to ascertain the accuracy of diagnoses, risk of facial paralysis in subgroups of individuals who may have comorbidities, existing predisposing factors to Bell palsy, and whether mild and transient cases were unreported in these studies.

Recent analysis of the mRNA COVID-19 vaccine trials has shown that the incidence of Bell palsy among vaccinated individuals was greater than among the general population. In addition, reports of Bell palsy cases with a temporal relationship to mRNA COVID-19 vaccine have also emerged outside of the vaccine trials.

Thus, despite the lack of an apparent signal suggesting an association between the mRNA COVID-19 vaccines and facial paralysis in the study by Renoud and colleagues, we need to be cognizant of the caveats and limitations of individual studies. While current data suggest that the risk of facial paralysis after mRNA COVID-19 vaccination appears low, further studies to analyze and compare the clinical histories, comorbidities, and neuroimaging and electrophysiological findings of patients with conventional Bell palsy and those who develop it after COVID-19 vaccination may help to provide further information on the possibility and risk of mRNA COVID-19 vaccine-related facial paralysis.

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Letters

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ter being derived from the literature, or preferentially, from recent and up-to-date health care databases. The use of historical rates as comparators has some limitations owing to the methods used to obtain the rates, heterogeneity of cases, population and clinical codes, and geographic and temporal variations. In a recent study, background rates of Bell palsy were calculated from 8 different countries, and ranged from 14 per 100,000 person-years to more than 200 per 100,000 person-years, depending on age, sex, and country. Notwithstanding these caveats, the best designed observed-to-expected studies to date, those performed by the US Centers for Disease Control and Prevention, did not find higher than expected rates of Bell palsy after mRNA COVID-19 vaccination.

Our study shows that the reporting rate of Bell palsy after mRNA COVID-19 vaccination is comparable with that of other viral vaccines, therefore suggesting that if this ADR does exist, its incidence rate is probably low. The aforementioned observed-to-expected report confirms this hypothesis, and the final conclusion will arise from large cohort pharmacoepidemiologic studies.

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Discrepancy in the Number of Patients in the Analyses in Study of Development and Validation of the Good Outcome Following Attempted Resuscitation Score

To the Editor On behalf of my coauthors, I write to explain corrections for an error in our Original Investigation, "Development and Validation of the Good Outcome Following Attempted Resuscitation (GO-FAR) Score to Predict Neurologically Intact Survival After In-Hospital Cardiopulmonary Resuscitation," that was published online on September 9, 2013, and in the November 2013 issue of JAMA Internal Medicine. This error was brought to the attention of the journal editors by an interested medical student 9 years after publication. There was a discrepancy in the number of patients in the bivariate and multivariate analyses that was caused by failure to exclude 138 patients with incomplete data in the bivariate analysis. The correct number included was 21,018, not 21,156. This error changed the percent mortality calculation by between 0.1% and 0.3% for each variable. This error had no effect on variable selection or the multivariate analysis, which are correctly reported. Table 2 with variables initially included in the multivariate model based on bivariate analysis has been corrected to only include the participants with complete data that were used to develop the prediction index. As far as I know, there are no other errors. The corrections do not change the overall findings and conclusions of the study, and I appreciate the opportunity to correct the article.

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CORRECTION

Error Due to Inclusion of Patients With Incomplete Data in an Analysis: In the Original Investigation, "Development and Validation of the Good Outcome Following Attempted Resuscitation (GO-FAR) Score to Predict Neurologically Intact Survival After In-Hospital Cardiopulmonary Resuscitation," published online on September 9, 2013, and in the November 2013 issue of JAMA Internal Medicine, there was an error in the number of patients included in the analysis reported in Table 2 that was caused by failure to exclude 138 patients with incomplete data in the bivariate analysis. The correct number included was 21,018, not 21,156. This error changed the percent mortality calculation by between 0.1% and 0.3% for each variable in Table 2 as explained in the accompanying Letter. Table 2 has been corrected following a previous correction to this article.

2. Ebell MH. Discrepancy in the number of patients in the analyses in study of development and validation of the Good Outcome Following Attempted Resuscitation score. JAMA Intern Med. Published online August 16, 2021. 10.1001/jamainternmed.2020.6664