

## Supplemental Online Content

Renoud L, Khouri C, Revol B, et al. Association of facial paralysis with mRNA COVID-19 vaccines: a disproportionality analysis using the World Health Organization pharmacovigilance database. *JAMA Intern Med*. Published online April 27, 2021. doi:10.1001/jamainternmed.2021.2219

### **eMethods.**

This supplemental material has been provided by the authors to give readers additional information about their work.

## eMethods.

### Cases

We extracted all cases of facial paralysis associated with mRNA vaccines reported in the WHO pharmacovigilance database, using the following MedDRA preferred terms (PTs): “facial nerve disorder”, “facial paralysis”, “facial paresis”, “facial spasm”, “oculofacial paralysis”, “VII<sup>th</sup> nerve injury”.

Two separate analyses were performed using only Facial Paralysis PT (narrow definition) and using the whole group of extracted PT (broad definition). In the broad definition, the number of cases in the control group included all types of facial paralysis terms whether or not they were reported with COVID vaccines.

### Control

Two separate analyses were performed using all other viral vaccines (ATC J07B) or influenza vaccines alone (ATC J07BB) as control groups.

### Disproportionality analysis

In this study, we used the bayesian neural network method which displays the best sensitivity and specificity among disproportionality methods.<sup>1</sup> A disproportionality signal was deemed significant if the lower boundary of the 95% credibility interval of the Information Component (IC<sub>025</sub>) was superior to 0<sup>2</sup>. Moreover, IC were adjusted and age and sex through stratification.<sup>3-5</sup>

Such analyses assume that the likelihood of reporting an event that occurs is similar between exposed and non-exposed cases. This assumption may be impacted by media attention on a given adverse drug reaction (ADR) or drug, selective reporting of more severe ADR or newer drugs, or according to reporter type. This hypothesis therefore needs to be checked and discussed in any disproportionality analysis.

### References

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