

# Orofacial adverse effects of COVID-19 vaccines exist but are rare

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## A commentary on

**Cirillo N.**

Reported orofacial adverse effects of COVID-19 vaccines: the knowns and the unknowns. *J Oral Pathol Med* 2021; **50**: 424-427.

## Abstract

**Data sources** The US Food and Drug Administration (FDA), Health Canada, European Medicines Agency (EMA)/European Commission and UK's Medicines and Healthcare products Regulatory Agency (MHRA).

**Study selection** Product monographs, product information and consumer medicine information for the BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) vaccines.

**Data extraction and synthesis** Reported side/adverse/undesirable effects concerning the orofacial region were extracted and tabulated. Results There were rare reports of adverse events affecting the orofacial region for both vaccines in their pertaining documents, including acute peripheral facial paralysis (Bell's palsy), facial swelling and swelling of the lips, face or tongue associated with anaphylaxis. There was heterogeneity in the acknowledgement of vaccine-related adverse events in North America compared with Europe.

**Conclusions** There are rare reports of orofacial adverse effects of two mRNA-based COVID-19 vaccines in their documents; however, there are inconsistencies in the description of these adverse effects in different countries.

## Commentary

With the COVID-19 pandemic emerging throughout the world in early 2020, many pharmaceutical companies in different countries tried to manufacture an effective vaccine against the SARS-CoV-2 virus which is responsible for the disease. After announcing the success of the clinical trials of some of these vaccines and regulatory approvals, countries started mass vaccination campaigns. Two of these early vaccines, BNT162b2 and mRNA-1273 (which are often known by their manufacturers' names: Pfizer-BioNTech and Moderna, respectively), are using a new technology that has not been tested on a global scale previously. This may cause vaccine hesitancy, which puts people in doubt about whether or not they receive a COVID-19 vaccine.<sup>1,2,3</sup> Therefore, knowing the adverse effects of the COVID-19 vaccines, especially new mRNA-based ones, will empower people against myths about COVID-19 vaccines.

## Practice points

- Official documents from the EU, UK, US and Canada regarding adverse effects of mRNA-based COVID-19 vaccines show that they may be related to rare orofacial complications.
- These orofacial complications include swelling of the face, lips, or tongue, Bell's palsy and, exclusively with the mRNA-1273 vaccine, swelling of the face in people who have had a facial cosmetic injection.



So far, there has been some information available regarding the adverse effects of the COVID-19 vaccines as they have not been tested in long-term use and phase IV clinical trials. Accordingly, both their safety and effectiveness are still under investigation. With emerging evidence that some COVID-19 vaccines may have links with some life-threatening adverse events,<sup>4,5,6,7</sup> people are more concerned about the safety of these vaccines, although the harms are very much fewer than the benefits.<sup>8,9</sup>

Cirillo<sup>10</sup> tried to collect all official information about COVID-19-related adverse events in the orofacial region. Instead of using statistical data, this study analysed the contents of product monographs, product information and consumer medicine information for the BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) vaccines from some official regulatory authorities, namely the US Food and Drug Administration (FDA), Health Canada, European Medicines Agency (EMA)/European Commission and UK's Medicines and Healthcare products Regulatory Agency (MHRA). The results of this study showed that these materials pointed out some rare orofacial adverse effects, including swelling of the face, lips or tongue (up to 1 in 1,000 people), facial drooping (Bell's palsy) and, exclusively with the mRNA-1273 vaccine, swelling of the face in people who

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have had a facial cosmetic injection. These side effects were not reported similarly in all official documents; for example, Bell's palsy was not mentioned in the information for patients in the US and Canada.

Although this method provides us with valuable information from trusted documents, there is a need for more accurate and quantitative methods regarding orofacial adverse effects of COVID-19 vaccines with valid national/international data. There have been some efforts recently in European countries.<sup>11</sup>

While all these documents are based on the high-quality large-scale phase III clinical trials, due to the inconsistencies in the description of these adverse effects, the overall quality of the result of this study was judged to be low. This means we need more high-quality and long-term research regarding the adverse effects of COVID-19 vaccines in the orofacial region. Until then, we should know that mRNA-based COVID-19 vaccines may be related to orofacial region swelling and Bell's palsy.

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