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Signaling COVID-19 vaccine adverse events

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Introduction: Statistical signal detection is a crucial tool for rapidly identifying potential risks associated with pharmaceutical products. The unprecedented environment created by the coronavirus disease 2019 (COVID-19) pandemic for vaccine surveillance predisposes commonly applied Signal detection methodologies to a statistical issue called the masking effect, in which signals for a vaccine of interest are hidden by the presence of other reported vaccines. This masking effect may in turn limit or delay our understanding of the risks associated with new and established vaccines.

Objective: The aim is to investigate the problem of masking in the context of COVID-19 vaccine signal detection, assessing its impact, extent, and root causes.

Methods: Based on data underlying the Vaccine Adverse Event Reporting System, three commonly applied statistical signal detection methodologies, and a more advanced regression-based methodology, we investigate the temporal evolution of signals corresponding to live largely recognized adverse and two potentially new adverse events.

Results: The results demonstrate that signals of adverse events related to COVID- 19 vaccines may be undetected or delayed due to masking when generated by methodologies currently utilized by pharmacovigilance organizations, and that a class of advanced methodologies can partially alleviate the problem. The results indicate that while masking is rare relative to all possible statistical associations, it is much more likely to in COVID-19 vaccine signaling, and that its extent, direction, impact, and roots are not static, hut rather changing in accordance with the changing nature of data.

Conclusion: Masking is an addressable problem that merits careful consideration, especially in situations such as COVID-19 vaccine safety surveillance and other emergency use authorization products.