

Review of: "[Viewpoint] Vaccination campaigns against Covid-19 may promote vaccine hesitancy toward well-established, safe, and effective vaccines"

Eugenio Serravalle

Potential competing interests: No potential competing interests to declare.

This is an interesting article leading to a general reflection on all vaccines and vaccinations.

There is not, indeed, a scientific controversy about vaccines and vaccinations themselves, with opposing scientific positions; the dispute is instead caused by using the scientific knowledge and its technical applications to address issues of social relevance. Vaccines are different from any other medical intervention: they act on healthy, not sick individuals, and this inevitably amplifies the relevance of adverse events. Imposing any obligation is not the solution to reduce vaccination hesitancy, while understanding the reasons behind that hesitancy would help. Hence the need to detect rare or poorly-defined adverse events: "we need to modernize vaccine pharmacovigilance methods to rebuild public confidence."

Besides the impact on target infectious diseases, vaccines can also have "non-specific effects" which, if real, could in theory be beneficial, neutral, or harmful, with the dramatic consequences recorded in some low-income countries, such as increased overall mortality after administration of some vaccines. However, current pharmacovigilance systems do not provide sufficient guarantee they can detect those effects; the several observational studies implemented are unable to establish causality, and the few RCTs are not characterized by sufficient size and follow-ups to identify and prove causality for those rare or uncommon non-specific effects for which a baseline incidence exists in any case.

Currently, there is a well-developed framework of rules in force for testing, approving, and regulating vaccines which, however, does not take into account the "non-specific effects" not related to target diseases. Yet, with what we know today, we are not optimally testing vaccines before their introduction. There is a growing body of evidence that vaccines have broad effects on the immune system and on the risk of unrelated infections. To optimize vaccine benefits, reduce possible harm, and maintain public trust, it is essential to document that a given vaccine has a net beneficial effect on overall health.

Chandler R. E. Modernising vaccine surveillance systems to improve detection of rare or poorly defined adverse events, *BMJ* 2019;365:l2268 doi: 10.1136/bmj.l2268 Pub: 31 May 2019

Christine Stabell Benn, Nelly Amenyogb, Anders Björkman, et al. Implications of Non-Specific Effects for Testing, Approving, and Regulating Vaccines *Drug Safety* (2023) 46:439–448 <https://doi.org/10.1007/s40264-023-01295-3>

