

Review of: "Measuring the efficacy of a vaccine during an epidemic"

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Potential competing interests: No potential competing interests to declare.

This well written and well structured paper addresses the issue of underestimation of vaccine effectiveness data originating from real world studies compared with efficacy results derived from ideal conditions and controlled circumstances.

The study refers to the issue of vaccine effectiveness in large cohort studies, where the presence of a large number of infectious cases in the population would lead to a systematic reduction in the estimate. The conclusion, overall, is that the magnitude of exposure to infection should be taken into account, as "vaccine effectiveness underestimates vaccine efficacy": this underestimation increases with the increasing fraction of infected individuals and with the severity of infection. Moreover, the issue of the time required for sufficient antibody production to be available is considered, whereby, in a phase immediately following an epidemic peak individuals will be exposed to the highest risk of exposure while they will be still unprotected/less protected.

As a general comment, as a reader, I found some difficulties with the use of the two crucial terms "vaccine effectiveness" and "vaccine efficacy" throughout the discussion and conclusions: in particular, in the first paragraph of the Conclusions section, a "systematic decrease on the estimated vaccine effectiveness" is cited, while in the final paragraph of the Introduction section, it is assumed that it is vaccine effectiveness that underestimates vaccine efficacy.

Some suggestions for review:

- Introduction

I would include additional literature references on efficacy and effectiveness in the Introduction section. I would add, among the causes of the variability between efficacy values, the variable of time since vaccination and the outcome considered: infection, illness, hospitalization in the medical area or intensive care unit, and death.

- Discussion

The comment in the last paragraph of the Discussion about behavioral changes that might result from the perception of greater proven safety by vaccinated subjects seems to me to be unrelated to the central discussion of the paper. I would also suggest including a short paragraph on the limitations of the work.

In addition, here are some minimal formatting/editorial details:

- affiliation N 3 is repeated and does not appear to be filled in
- in the abstract there is a repetition in the third line
- in the last paragraph of the introduction, third to last line, there seems to be a missing "that" before "the effectiveness"

I state finally that I do not have the statistical expertise to evaluate the methodical aspects on the proposed model.

Overall, this is a valuable paper, ready as a high level technical publication.