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Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Letter to the Editor

Using observational data to prioritise COVID-19 vaccination strategies: opportunity or necessity?

Since the initial reports of cases of severe acute respiratory syndrome coronavirus 2 infection one year ago, the virus has spread worldwide, causing 1.70 million deaths in 191 countries.

Social measures to halt virus transmission will now be complemented by plans of large-scale vaccination programmes. Logistic challenges in distributing large quantities of vaccines, however, conflict with the need for a rapid access to them for as wide as possible a segment of the population initially targeted at the highest risk groups. Strategies therefore need to be developed to ensure vaccinations are targeted to the highest risk groups.

While non-medical factors should be considered when delineating such strategies, two elements are instrumental in the definition of any prioritisation list: (1) the risk of infection and severe COVID-19 and (2) the efficacy and safety of vaccines in specific groups of individuals. Observational studies have identified several prognostic factors (i.e., age, obesity, chronic diseases, ethnicity, healthcare/social care professions, occupation) associated with a higher risk of COVID-19 or COVID-19–related death; regardless of their causative role, their presence helps to identify vulnerable people. This is reflected, for example, in the advices on priority groups for COVID-19 vaccination in several countries.

Although observational studies are sufficient to identify risk factors, randomised controlled trials (RCTs) are required to estimate the efficacy of therapies including a vaccine. RCTs are primarily designed to estimate an 'average' effect in the trial population; assuming the same efficacy applies across heterogeneous groups of patients (possibly also in those not included in the trial), it is possible to calculate the absolute benefit using the risk quantified in observational studies and the total burden of disease that is preventable by vaccination, thus allowing an evidence-based approach in ranking priority groups.

Reporting efficacy by subgroups of patients at higher or lower risk of COVID-19 outcomes in RCTs would help to better quantify the absolute benefits. However, given the limited availability, to date, of vaccine efficacy data in subgroups and the limited statistical power of these analyses, observational data collected during the next few months of vaccination may also clarify if the efficacy is lower in some subgroups and give an estimate of the efficacy to effectiveness gap in the real world.

Finally, RCTs are designed to evaluate the safety of the vaccines; the probability of identifying safety signals, however, is higher in large observational studies including diverse populations, in contrast with the more homogenous patients and the comparatively smaller sample size of RCTs, which hamper the possibility to observe very rare but potentially serious side-effects.

Research using observational data has been pivotal during the last twelve months of the pandemic; if properly conducted, it will remain a necessity, rather than a simple opportunity, in the forthcoming months to generate evidence for an equitable, while safe and effective, vaccination strategy.

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