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Preparing for the next pandemic: insights from the EvOLVE Scoping Review.

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Has this research been submitted or presented elsewhere? If so where and when? The study protocol has been published: Stehlik P, Dowsett C, Camacho X, *et al* **Evol**ution of the data and methods in real-world COVID-19 vaccine effectiveness studies on mortality: a **sc**oping **r**eview protocol *BMJ Open* 2024; 14**:**e079071. doi: 10.1136/bmjopen-2023-079071

Some of the results have been presented at two conferences:

1. MI-CRE 2024 Annual Research Symposium and Policy Forum 14-15 August 2024
2. the Ponfifical Academy of Sciences "Workshop on SARS-COV-2 Health Policies, Vaccination and Long COVID: Achievements and Challenges" 19-20 November 2024

Abstract

Background and Aims: During the COVID-19 pandemic, real-world vaccine effectiveness (VE) studies were instrumental in informing policy. We summarised this literature to understand how it evolved and provide insights into evidence generation during future pandemics.

Design and Methods: We identified studies from the Johns Hopkins VIEW-hub database, which COVID19 VE studies from 13 databases, from inception to 10th Aug 2023. We included observational studies of COVID-19 VE on mortality. We excluded duplicate studies or those without methods reported.

A single reviewer extracted study characteristics, data sources, design, and analytic methods, which were checked for accuracy by another reviewer. Discrepancies and key messages were discussed in a small group setting with methodological and analytic experts. Here we present key highlights relevant to policy makers.

Results: Eighty-five studies met the inclusion criteria. These were conducted from February 2021 to May 2023. Twenty-nine (34%) studies were from low- and middle-income countries.

Sixty-one (72%) were cohort studies, 17 (20%) some variation of a test-negative study, 7 (9%) used other designs. Five studies (6%) used aggregate or unlinked surveillance data, 32 (38%) used analytic platforms with pre-linked electronic health records (EMR), 47 (55%) linked data from a variety of sources, one did not report data sources. COVID19 mortality was defined using a death certificate in 29 (34%) studies and 35 (41%) used a time-based definition.

Most studies (33, 57%) were publicly funded; 4 (5%) were funded by industry. Sixty-four (75%) underwent a full ethics review, 13 (16%) were exempt or had pre-existing approvals granted, 8 did not provide an ethics statement. One study, (1%) required individual patient consent, and 35 (41%) did not report on consent.

Conclusions: We provide a historical snapshot of the data and study designs used to generate real-world COVID-19 VE on mortality. It demonstrates a variety of approaches on measuring VE in local contexts depending on data infrastructure (from pre-linked EMR analytic platforms to aggregate or unlinked surveillance data), and that this can be done safely without slowing evidence generation. It also illustrates the democratisation of research capabilities across countries of varying wealth through access to linked routinely collected data.