World Health Organization
REGIONAL OFFICE FOR Europe

Estimating COVID-19 vaccine effectiveness against severe acute respiratory infections (SARI) hospitalisations associated with laboratory-confirmed SARS-CoV-2

An evaluation using the test-negative design

Guidance Document

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CORRIGENDA

Estimating COVID-19 vaccine effectiveness against severe acute respiratory infections (SARI) hospitalisations associated with laboratory-confirmed SARS-CoV-2. An evaluation using the test-negative design. Guidance document.

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These corrections have been incorporated into the electronic file on 09 July 2021.

- Page 6. The phrase “using existing SARI surveillance systems” was removed because it was redundant.
- Page 7. “See Section 4.4” was deleted
- Page 7. The phrase “VE of” was changed to “VE against.”
- Page 11. The reference in 3.12 was changed from Annex 2 to Annex 1.
- Page 11. In section 3.12, section references for “influenza and other viruses” and “vaccinations and antivirals” were removed.
- Page 11. In section 3.12, the functional status or proxy by residence type was changed to section 3.9.7
- Page 12. In section 3.12.3, the section reference for smoking history was removed

- Page 19. In section 3.13.4, Table 3, parentheses were added to the first row to indicate “interquartile range”

- Page 22. In section 4.1.2, the second-to-last sentence should read “which may increase their likelihood to be infected by SARS-CoV-2.”

- Page 18. In section 4.1.4, an “s” was added to the word “control.”

- Page 18. In section 4.1.4, “increase CVE” was changed to “decrease CVE” at the end of the first paragraph.
- Page 28. In Annex 2, “heart failure” was deleted the second time it appeared.

- Page 31. The word “numeric” was added in the same row as “residence.”

- Page 33. The second “Hypersensitivity pneumonitis due to organic dust” was removed

- Page 33. The Tuberculosis row was shaded in grey because it’s optional.

- Page 42. Section M changed to “Public Health and Social Measures.”

- Page 43. The reference 3.12.7 was changed to “3.12.6”

- Page 44. The following text was added: “as described in the main protocol” and the specific reference was deleted.

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Contents

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Abbreviations

COVID-19	Coronavirus disease 2019
CVE	COVID-19 vaccine effectiveness
EEA	European Economic Area
ECDC	European Centre for Disease Prevention and Control
EU	European Union
GP	General practitioner
ICD	International classification of diseases
ILI	Influenza-like illness
I-MOVE	Influenza – Monitoring Vaccine Effectiveness in Europe
MS	Member States
OR	Odds ratio
RF	Risk factor
RT- PCR	Real-time polymerase chain reaction
SARI	Severe acute respiratory infection
SARS-CoV-2	Severe acute respiratory syndrome – coronavirus 2
VE	Vaccine effectiveness

Executive Summary

Many critical questions remain about the effectiveness of COVID-19 vaccines in real-world settings. These questions can only be answered in post-introduction vaccine effectiveness studies.

This guidance document outlines an approach to leverage existing surveillance systems for Severe Acute Respiratory Infection (SARI) to estimate COVID-19 vaccine effectiveness (VE) in preventing SARI associated with laboratory-confirmed SARS-CoV-2. The approach uses the test-negative design to evaluate VE; cases are SARI patients who tested positive for SARS-CoV-2, and controls are SARI patients who tested negative for SARS-CoV-2.

As in current SARI surveillance, hospitalized patients with SARI at designated SARI surveillance hospitals can be enrolled if they meet the WHO case definition for SARI. A respiratory specimen should be collected from SARI patients within 48 hours of admission to the hospital. In addition, data can be collected about the patient's sociodemographic characteristics, history of acute illness, clinical course in hospital, and the COVID-19 vaccine history.

The document proposes that enhanced SARI surveillance to allow for VE estimates be implemented for a minimum of 6 months but ideally longer. The methods described in the guidance document are also appropriate for estimating influenza VE. The document also proposes that a pooled data analysis be conducted for the WHO/Europe region, which requires that SARI surveillance systems collect a minimum data set of similar variables.