**STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) checklist with recommended additional elements for reporting COVID-19 vaccine effectiveness studies.**

| SECTION/TOPIC | STROBE ITEM NO | STROBE | COVID-19 VE STUDIES | REF PAGE* |
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| **TITLE AND ABSTRACT** | | | | |
| TITLE/ABSTRACT | 1 | Indicate the study's design with a commonly used term in the title or the abstract | Specify study design (e.g., case-control, TND or cohort) | 1 |
| | | Provide in the abstract an informative and balanced summary of what was done and what was found | Report vaccine type(s), outcome, target vaccine groups evaluated, study location, VE and 95% confidence intervals | 1 |
| **INTRODUCTION** | | | | |
| BACKGROUND/ RATIONALE | 2 | Explain the scientific background and rationale for the investigation being reported | Mention efficacy results from pivotal clinical trial that led to EUL/EUA or licensure of vaccine being studied | 2 |
| | | | Describe specific vaccine products in use, timeline of introduction, targeted populations and coverage, NPI measures in place in study area | 4 |
| | | | Describe COVID-19 epidemiology preceding and during period of study, including baseline seroprevalence in the target population if known, disease activity, and predominant variants during the study | 4, Figure 2 |
| OBJECTIVES | 3 | State specific objectives, including any prespecified hypotheses | Was study done to provide local/subpopulation VE estimates or answer global evidence gap in VE data? | 2 |
| **METHODS** | | | | |
| STUDY DESIGN | 4 | Present key elements of study design early in paper | TND, traditional case-control, cohort, other | 2 |
| SETTING | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | Describe the enrollment setting (e.g. SARI surveillance, hospitalized patients), location or region<br>COVID-19 incidence at time of study, vaccines in use, introduction dates, and timing of rollout in target groups, NPI measures in place, and common circulating SARS-CoV-2 variants | 2 |
| | | | Report time period when data were collected | 2 |
| PARTICIPANTS | 6 | Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of followup. | Report specific clinical case definition used for enrollment | 2 |
| | | | Report definition of severity used | 3 |
| | | Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls | Describe eligible study population in terms of age and vaccine target groups (e.g., HWs, chronic medical conditions) and exclusion criteria | 4 |
| VARIABLES | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | COVID-19 vaccine variables<br>Report definition for vaccination status, including exclusions based on vaccine timing (e.g., receipt of vaccine < 14 days of illness onset) and fully vs. partially vaccinated, dose interval COVID-19 outcomes | 3 |
| | | | Report sensitivity and specificity of diagnostic test used; if rapid antigen test, give test name and antigen target; | N/A as RT-PCR has known Se and Sp |
| | | | Indicate if COVID-19 result known prior to or after enrollment. Explain how possible vaccine reactions were handled in TND studies (e.g., exclude recent vaccinees tested for possible febrile reaction to vaccine) Covariates | 2 |
| | | | Report covariates assessed for confounding, and if and how adjusted for | 4 |

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| | | | Report the specific cut points used for continuous variables that are categorized (e.g. age groups). | 2,3 |
| | | | Provide the list of conditions included as ‘‘high risk” | 2 |
| | | | Provide the unit of time if adjusting for calendar time. | 2 |
| | | | Describe how prior COVID-19 infection was defined | N/A |
| DATA SOURCES/ MEASUREMENT | 8 | For each variable of interest, give sources of data and details of methods of assessment (measurement). | *COVID-19 vaccine*<br>Report source of vaccination data (e.g., vaccine card, medical record, registry, provider report, patient report, or some combination of the above). | 2 |
| | | Describe comparability of assessment methods if there is more than one group | List the type and brand of vaccine (lot number if available). | 3 |
| | | | Report recommended schedule for vaccination (number of doses and time interval between doses) | 3 |
| | | | *COVID-19 outcomes*<br>Report procedures for collection of respiratory samples and RT-PCR testing, include type of respiratory samples collected (e.g. nasal, nasopharyngeal), type of swab used (e.g. flocked), transport media (e.g. universal transport media or report if dry swabs were used) and maximum interval from onset to swab collection; | 3 |
| | | | Report up to how many days before enrollment a positive COVID-19 test was acceptable; Were subjects with compatible clinical illness without lab confirmation enrolled? | N/A |
| BIAS | 9 | Describe any efforts to address potential sources of bias | Report if prior COVID-19 infection and exposure risk to COVID-19 (e.g., mask-wearing) were assessed and how handled | N/A |
| STUDY SIZE | 10 | Explain how the study size was arrived at | Adjust sample size calculation to expected COVID-19 incidence and estimated VE from clinical trial | N/A |
| QUANTITATIVE VARIABLES | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groups were chosen and why | Report the specific cut points used for continuous variables that are categorized (e.g. age groups). Provide the unit of time if adjusting for calendar time | 2 |
| STATISTICAL METHODS | 12 | Describe all statistical methods, including those used to control for confounding | Describe the specific regression method used (e.g. logistic regression) and confidence limits methodology | 3 |
| | | | Report the time periods for which data were analyzed and if COVID-19 was circulating throughout | 2 |
| | | | Specify any matching variable (e.g. time) and whether regression model accounts for matching | 2 |
| | | | Specify how covariates assessed for inclusion in the model and final covariates included | 4 |
| | | | Describe how partially vaccinated persons were handled in the analysis (e.g., one dose) | 3 |
| | | | Describe how data were pooled if gathered from multiple sites and measure of heterogeneity calculated | N/A |
| STATISTICAL METHODS | 12 | Describe any methods used to examine subgroups and interactions | Describe any analyses of subgroups (e.g. age groups, chronic conditions, HWs) | 4, Table 1 |
| | | | Describe interactions assessed (e.g. prior COVID-19 infection) | N/A |
| | | Explain how missing data were addressed | Describe whether a complete case analysis was used or if missing data were imputed. Name | 4 |

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| | | | the package used for imputation (e.g. ICE in Stata). | |
| | | Cohort study—If applicable, explain how loss to follow-up was addressed<br>Case-control study—If applicable, explain how matching of cases and controls was addressed | In case-control studies, if more than one control group enrolled, explain rationale. | N/A |
| | | Describe any sensitivity analyses | For example, excluding verbal reports of vaccination; limited to positive test within 72 h of enrollment; limited to PCR + only (if rapid antigen tests included) | 4 |
| OTHER | | | Indicate if and where study protocol and/or study data are publicly available | 7 |
| **RESULTS** | | | | |
| PARTICIPANTS | 13 | a) Report numbers of individuals at each stage of study— e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completed follow-up, and analyzed | | 4 |
| | | b) Give reasons for non-participation at each stage | | N/A |
| | | c) Consider use of a flow diagram | | |
| DESCRIPTIVE DATA | 14 | a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders | Describe percentage of each COVID-19 vaccine used in the study population | Table 1 |
| | | | Report number of participants who received only one dose of two dose schedule, and if different vaccines given for each dose | 4 |
| | | | Describe seroprevalence of study population, if available | N/A |
| | | b) Indicate number of participants with missing data foreach variable of interest | | N/A |
| | | c) Cohort study—summarize follow-up time (e.g., average and total amount) | | N/A |
| OUTCOME DATA | 15 | Cohort study—Report numbers of outcome events or summary measures over time<br>Case-control study—Report numbers in each exposure category, or summary measures of exposure | Describe number/percent of tests which were PCR, rapid antigen test, other. | Table 1 |
| | | | Report COVID-19 genomic information among vaccine failures, if available. Particularly variants of concern. | N/A |
| MAIN RESULTS | 16 | a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence intervals). Make clear which confounders were adjusted for and why they were included | Report adjusted VE and 95% CI by vaccine type | 5 |
| | | | Report adjusted VE and 95% CI for target groups separately, if sufficient power | 5 |
| | | | Report heterogeneity statistics for pooled data | N/A |
| | | b) Report category boundaries when continuous variables were categorized | | Table 1 |
| | | c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | | NNV reported |
| OTHER ANALYSES | 17 | Report other analyses done—e.g. analyses of subgroups and interactions, and sensitivity analyses | Report age-stratified VE and 95% CI estimates separately | 5 |
| | | | Report separate VE and 95% CI among those with one dose, two doses and at least one dose COVID-19 vaccines | 5 |
| | | | Report separate VE and 95% CI by SARS-CoV-2 variant if sufficient power | N/A |

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| **DISCUSSION** | | | | |
| KEY RESULTS | 18 | Summarize key results with reference to study objectives | | 6 |
| LIMITATIONS | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | Specifically discuss potential biases affecting COVID-19 VE studies, including health-seeking bias, misclassification bias, diagnostic bias | 5 |
| INTERPRETATION | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | Explain potential differences in study VE from efficacy in relevant clinical trials (e.g., different target group, different outcome, immunization system factors) | 5 |
| GENERALIZABILITY | 21 | Discuss the generalizability (external validity) of the study results | Was baseline seroprevalence different from other settings? Predominant viral variant found in other settings? | 5 |
| **OTHER INFORMATION** | | | | |
| FUNDING | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | | 7 |

* REF PAGE- Reference page in the main manuscript file.