STROBE Statement—checklist of items that should be included in reports of observational studies

Section/item	Item No	Recommendation	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 2	section of Abstract
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2-3	the Methods and Results in Abstract
Introduction				
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 3-4	section of Introduction
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 4	the second paragraph of Introduction
Methods				
Study design	4	Present key elements of study design early in the paper	Page 4	the section of study population of Methods
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 4-6	the section of study population,follow-up and grouping in Method
Participants	6	(a) ***Cohort study***—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up ***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 ***Cross-sectional study***—Give the eligibility criteria, and the sources and methods of selection of participants	Page 4-6	the section of study population,follow-up and grouping and definition of ISR in Method
		(b) ***Cohort study***—For matched studies, give matching criteria and number of exposed and unexposed ***Case-control study***—For matched studies, give matching criteria and the number of controls per case	Page 4-6	the section of study population,follow-up and grouping in Method
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 4-8	the section of Method
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 4-8	the section of Method
Bias	9	Describe any efforts to address potential sources of bias	Page 4-8	the section of Method
Study size	10	Explain how the study size was arrived at	Page 4-5	the section of study population of Methods
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 8-9	the section of Statistical analysis

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 8-9	the section of Statist ical analysis
		(b) Describe any methods used to examine subgroups and interactions	Page 8-9	the section of Statist ical analysis
		(c) Explain how missing data were addressed	Page 8-9	the section of Statist ical analysis
		(d) ***Cohort study***—If applicable, explain how loss to follow-up was addressed ***Case-control study***—If applicable, explain how matching of cases and controls was addressed ***Cross-sectional study***—If applicable, describe analytical methods taking account of sampling strategy	Page 8-9	the section of Statist ical analysis
		(e) Describe any sensitivity analyses	Page 8-9	the section of Statist ical analysis
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 5	the section of study p opulation of Methods
		(b) Give reasons for non-participation at each stage	Page 5	the section of study p opulation of Methods
		(c) Consider use of a flow diagram		Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 9-10	the baseline character istics in Results
		(b) Indicate number of participants with missing data for each variable of interest	Page 5	the section of study p opulation of Methods
		(c) ***Cohort study***—Summarise follow-up time (eg, average and total amount)	N/A	
Outcome data	15*	***Cohort study***—Report numbers of outcome events or summary measures over time	N/A	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	Page 6	the section follow up and grouping in Method
		Cross-sectional study—Report numbers of outcome events or summary measures	N/A	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page 10-11	the section of the pre dictor of ISR and clin ical prediction model
		(b) Report category boundaries when continuous variables were categorized	Page 9-10	e characteristics in R esults
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	None	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 11	dictor of ISR in Resul ts
Discussion				
Key results	18	Summarise key results with reference to study objectives	Page 14-15	the second paragraph i n Page 14
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	Page 16	the first paragraph in Page 16

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 16	the section of conclusions
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 16	the first paragraph in Page 16
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	Page 16-17	the section of Fundings

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.