Quality control instruments: Research checklists

STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) Statement [29]

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (**page iii)**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **(pages 19–22)**
Introduction		
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported **(pages 23–35)**
Objectives	3	State specific objectives, including any prespecified hypotheses **(pages 34–35, table 2)**
Methods		
Study design	4	Present key elements of study design early in the paper **(page 37)**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection **(page 37–43, tables 3 and 4)**
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 **(not applicable)** *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants **(pages 37–40)**

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	Item No	Recommendation
Participants (continued)		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed **(not applicable)** *Case-control study*—For matched studies, give matching criteria and the number of controls per case **(not applicable)**
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable **(figure 11)**
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 **(table 4)**
Bias	9	Describe any efforts to address potential sources of bias **(pages 44 and 47)**
Study size	10	Explain how the study size was arrived at **(page 40)**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why **(page 47)**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **(pages 45–47)**
		(*b*) Describe any methods used to examine subgroups and interactions **(not applicable)**
		(*c*) Explain how missing data were addressed **(page 47)**
		(*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 **(not applicable)**
		(**e**) Describe any sensitivity analyses **(not applicable)**

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	Item No	Recommendation
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 40, table 3)**
		(b) Give reasons for non-participation at each stage **(page 40)**
		(c) Consider use of a flow diagram **(table 3**)
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders **(tables 3, 7, and 8)**
		(b) Indicate number of participants with missing data for each variable of interest **(table 7)**
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount) **(not applicable)**
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time **(not applicable)**
		Case-control study—Report numbers in each exposure category, or summary measures of exposure **(not applicable)**
		Cross-sectional study—Report numbers of outcome events or summary measures **(pages 49–174, tables 9–19)**
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 **(pages 49–174, tables 9–19)**
		(*b*) Report category boundaries when continuous variables were categorized **(table 7)**

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	Item No	Recommendation
Main results (continued)		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period **(not applicable)**
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses **(not applicable)**
Discussion		
Key results	18	Summarise key results with reference to study objectives **(pages 176, 184–185, 188)**
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 **(pages 191–193)**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence **(pages 175–198)**
Generalisability	21	Discuss the generalisability (external validity) of the study results **(pages 191–193)**
Other information		
Funding	21	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 **(not applicable)**

*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.

Standards for Reporting Qualitative Research (SRQR[a]) [66]

	Page/line no(s).
Title and abstract	
Title—Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	Page iii
Abstract—Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	Pages 19–22
Introduction	
Problem formulation—Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	Pages 23–35
Purpose or research question—Purpose of the study and specific objectives or questions	Pages 34–35, table 2
Methods	
Qualitative approach and research paradigm—Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., post-positivist, constructivist/interpretivist) is also recommended; rationale[b]	Page 37, table 2, figure 10
Researcher characteristics and reflexivity—Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	Page 47
Context—Setting/site and salient contextual factors; rationale[b]	Table 2
Sampling strategy—How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale[b]	Pages 37–41, table 3
Ethical issues pertaining to human subjects—Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	Page 38
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	Page/line no(s).
Methods (continued)	
Data collection methods—Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale[b]	Pages 40–43, tables 3 and 4
Data collection instruments and technologies—Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Page 41, table 4
Units of study—Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Tables 2,3,5,7, and 8
Data processing—Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	Page 44
Data analysis—Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale[b]	Pages 44–47, figure 11
Techniques to enhance trustworthiness—Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale[b]	Page 44
Results/findings	
Synthesis and interpretation—Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Pages 49–174, tables 9–20
Links to empirical data—Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Pages 49–174, tables 9–20
Discussion	
Integration with prior work, implications, transferability, and contribution(s) to the field—Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	Pages 175–198
Limitations—Trustworthiness and limitations of findings	Pages 191–193

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	Page/line no(s).
Other	
Conflicts of interest—Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	There were no conflicts of interest
Funding—Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Not applicable

[a] The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

[b] The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

http://www.equator-network.org/reporting-guidelines/srqr/