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# Practical



# STROBE

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## *STROBE Statement*

Strengthening the reporting of observational studies in epidemiology

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# Observational studies

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- **Transparent reporting is particularly important for observational studies**
  - Vulnerable to bias and confounding
  - Findings are often over-interpreted
  - Findings often generate health scares



# Scope of STROBE

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- **Epidemiological research comprises several study designs and multiple topic areas**
- **Initial restriction to three major areas**
  - cohort, case-control, and cross-sectional studies
- **Later extensions to other study designs are expected**
  - STREGA for genetic association studies (published 2009)
  - Nested case-control studies
  - ...



# Final STROBE checklist

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## **TITLE and ABSTRACT**

### **INTRODUCTION**

Background/rationale

Objectives

### **METHODS**

Study design

Setting

Participants

Variables

Data sources/measurement

Bias

Study size

Quantitative variables

Statistical methods

## **RESULTS**

Participants

Descriptive data

Outcome data

Main results

Other analyses

## **DISCUSSION**

Key results

Limitations

Interpretation

Generalisability

## **OTHER INFORMATION**

Funding



# Some key items

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## Item 7 Variables

Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.

## Item 9 Bias

Describe any efforts to address potential sources of bias.



# Reporting for key subgroups

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- Some items have the attached note:

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

## *Examples:*

**14a Give characteristics of study participants (eg, demographic, clinical, social) and information on exposures and potential confounders.**

**14b Indicate the number of participants with missing data for each variable of interest.**



# Design-specific items

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- **Participants**
- **Statistical methods**
- **Descriptive data**
- **Outcome data**





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# STROBE

## Practical



# **Associations of depression and depressive symptoms with preeclampsia: Results from a Peruvian case-control study**

Chunfang Qiu<sup>1, \*</sup>, Sixto E. Sanchez<sup>2</sup>, Nelly Lam<sup>3</sup>, Pedro Garcia<sup>3</sup>, Michelle A. Williams<sup>1,4</sup>



STROBE Statement—Checklist of items that should be included in reports of *case-control studies*

	Item No	Recommendation
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
<b>Introduction</b>		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
<b>Methods</b>		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) 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
		(b) For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable



# For selected items ...

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- **Is there text relating to the item?**
- **Does the text tell us what we need to know?**



# STROBE

## Item 5. Setting

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**Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection**

**Can you locate any text about this issue in the report?**



# STROBE

## Item 5. Setting

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Qiu et al

**“This case-control study was conducted at the Materno Perinatal Institute of Lima and the Dos de Mayo Hospital in Lima, Peru, from May 2004 through October 2005. Both institutions are operated by the Peruvian government and are primarily responsible for providing maternity services to low income women residing in Lima.”**

**Does the text tell us what we need to know?**



# STROBE

## Item 6a. Participants

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**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**

**Can you locate any text about this issue in the report?**



# STROBE

## Item 6a. Participants

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### Qiu et al

**“Cases** were selected from those women with a diagnosis of preeclampsia. Potential preeclampsia cases were identified by daily monitoring of all new admissions to antepartum wards, emergency room wards, and labor and delivery wards of the study hospitals. Study subjects were recruited during their hospital stay. Study personnel made periodic visits to each ward in a fixed order for the purposes of identifying potential cases and controls for the present study. Preeclampsia was defined by ...”

**“Controls** were women with pregnancies uncomplicated by pregnancy-induced hypertension or proteinuria. Each day during the enrollment period, controls were numbered in the order in which they were admitted and identified. Subsequently, they were approached in the order in which research personnel identified them.”

**Does the text tell us what we need to know?**





# STROBE

## Item 10. Study size

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**Explain how the study size was arrived at**

**Can you locate any text about this issue in the report?**



# STROBE

## Item 10. Study size

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Qiu et al

?

Does the text tell us what we need to know?



# STROBE

## Item 13. Participants

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**(a) Report numbers of individuals at each stage of study—e.g. numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed**

**(b) Give reasons for non-participation at each stage**

**(c) Consider use of a flow diagram**



What we'd like to see:

What do they give us?

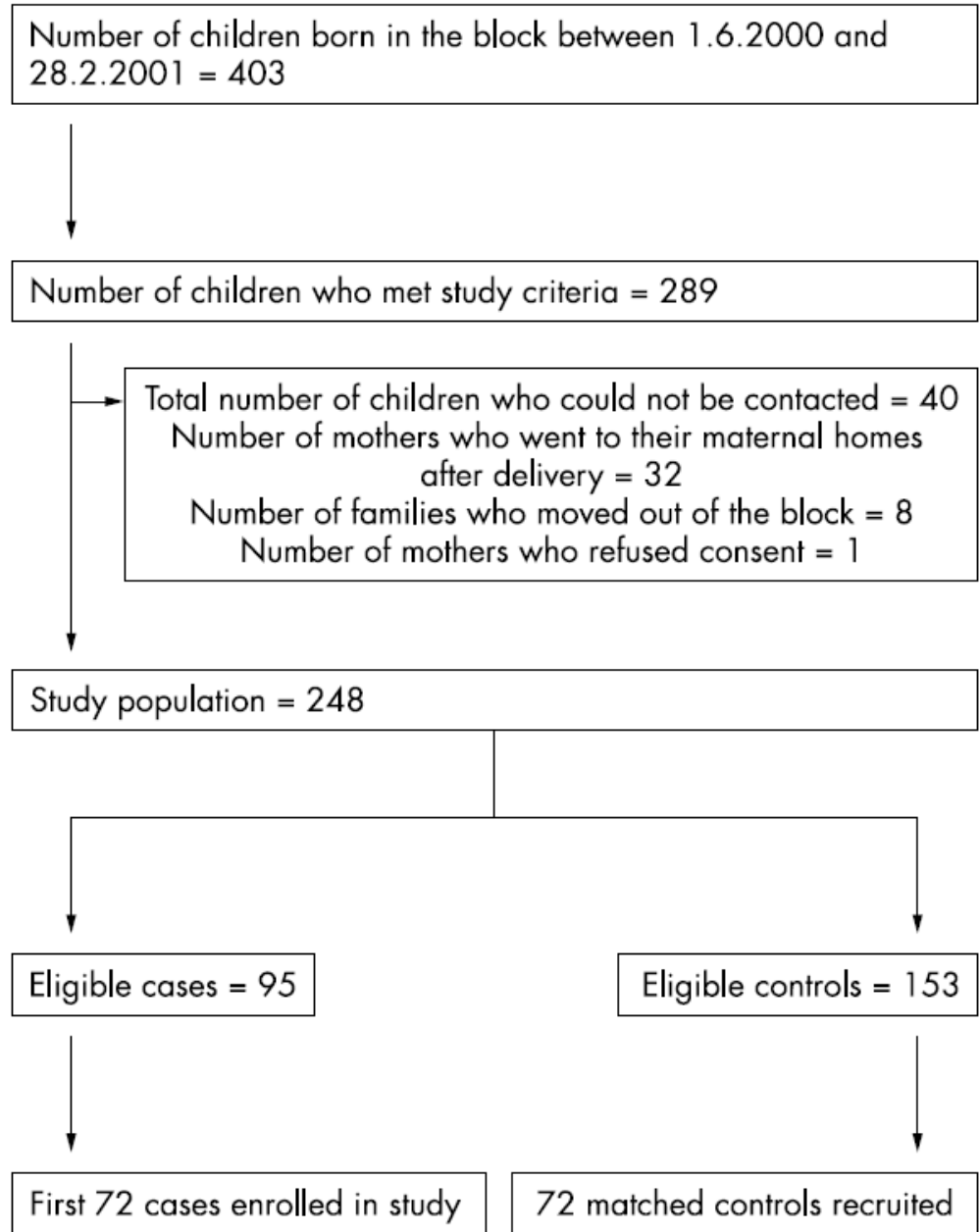


Figure 1 Flow chart of recruitment of cases and controls.



# Qiu et al

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“Approximately 95% of eligible cases approached and asked to participate in the study elected to do so.”

“Of the 362 controls approached, 337 (93%) agreed to participate in the study.”

**Does the text tell us what we need to know?**



# STROBE

## Item 19. Limitations

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**Discuss limitations of the study, taking into account sources of potential bias or imprecision.**

**Discuss both direction and magnitude of any potential bias**

**Can you locate any text about this issue in the report?**



# Qiu et al

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“First, our analyses are based on cross-sectionally collected data, which may be subject to recall bias. There has been one longitudinal study of Finnish women [6]; however, more longitudinal studies are needed to re-examine the potential causal relation between maternal experience of depression and preeclampsia risk in different populations.

Second, we used a depression screening instrument to categorize participants according to depression/depressive symptoms. Participants did not have formal diagnostic examinations. As a result, some misclassification is possible. ... In addition, our assessment of maternal depression and depressive symptoms was limited to the duration of the pregnancy.

Last, although we adjusted for multiple confounding factors, as with all observational studies, we cannot exclude the possibility of some residual confounding.”

**Does the text tell us what we need to know?**



# History of paper by Qiu et al

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- **Submission May 2007**
- **Peer reviews, x2**
  - Did not detect many of the issues
- **Published in *BMC Womens Health*, Sept 2007**





Research article

Open Access

## Associations of depression and depressive symptoms with preeclampsia: results from a Peruvian case-control study

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# Closing Comments on Checklists

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- They help **AUTHORS** ensure that they have addressed important issues in the report of their study
- They help **PEER REVIEWERS** and **EDITORS** by reminding them what issues should be addressed
- Checklist indicate minimum to be reported: **“Necessary but not sufficient!”**

