

# Methodological Evaluation of Observational Research (MEVORECH)—Observational Studies of Risk Factors of Chronic Diseases

## Instructions :

Please review the checklist and mark quality items that not reported and flaws in external or internal validity if present.

### Descriptive

Journal of publication \_\_\_\_\_

Year of publication \_\_\_\_\_

Funding of study \_\_\_\_\_

Role of funding organization in data analysis and interpretations of the results \_\_\_\_\_

Conflict of interest \_\_\_\_\_

Ethical approval of the study \_\_\_\_\_

### Aim of the study

Aim was not stated	<input type="checkbox"/>	Poor reporting
Included association with risk factors without clear definition of the target population	<input type="checkbox"/>	Minor flaw

### Objectives

Not clear statement	<input type="checkbox"/>	Poor reporting
Estimation of the association with prevalence of chronic conditions	<input type="checkbox"/>	
Estimation of the association with incidence of chronic conditions	<input type="checkbox"/>	

### Design

Not clear statement about the study design	<input type="checkbox"/>	Poor reporting
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## External Validity

### Sampling of the subjects by investigators

#### General population based

Not reported	<input type="checkbox"/>	Poor reporting
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#### Nongeneral population based sampling method

Not reported	<input type="checkbox"/>	Poor reporting
Convenient	<input type="checkbox"/>	Minor flaw
Self selection	<input type="checkbox"/>	Minor flaw

#### Nongeneral population-based sampling frame

Not reported	<input type="checkbox"/>	
Medical records	<input type="checkbox"/>	Major flaw
Insurance claims	<input type="checkbox"/>	Major flaw
Work place	<input type="checkbox"/>	Major flaw
Health care based (clinics, hospitals)	<input type="checkbox"/>	Major flaw

**For case-control studies**

Sampling of controls are not clearly reported	<input type="checkbox"/>	Poor reporting
Sampling of controls from different population as cases	<input type="checkbox"/>	Major flaw
Sampling of controls from health care related sources (out-clinic or in-clinics, health care claims)	<input type="checkbox"/>	Minor flaw

**Assess bias**

**Assessment of sampling bias (failure to ensure that all members of the reference population have a known chance of selection in the sample)**

No information about sampling bias	<input type="checkbox"/>	Poor reporting
The authors did not assess sampling bias	<input type="checkbox"/>	Minor flaw

**Response rate in total sample (cut off of acceptable response rate depend on the target population)**

Not reported	<input type="checkbox"/>	Poor reporting
<40 (or less than cut off specific for the target population) %	<input type="checkbox"/>	Major flaw

**Response rate in race subgroups (if applicable)**

Not reported	<input type="checkbox"/>	Poor reporting
<40 (or less than cut off specific for the target population) %	<input type="checkbox"/>	Major flaw

**Response rate in other subgroups (if applicable)**

Not reported	<input type="checkbox"/>	Poor reporting
<40 (or less than cut off specific for the target population) %	<input type="checkbox"/>	Major flaw

**Exclusion rate from the analysis**

Not reported	<input type="checkbox"/>	Poor reporting
>10%	<input type="checkbox"/>	Major flaw

**Exclusion rate in subgroups (if applicable)**

Not reported	<input type="checkbox"/>	Poor reporting
>10%	<input type="checkbox"/>	Major flaw

**Subject flow (the acceptable ranges can be specific for the area of research)**

Not applicable for study design	<input type="checkbox"/>	
Number screened not reported	<input type="checkbox"/>	Poor reporting
Number eligible not reported	<input type="checkbox"/>	Poor reporting
Number enrolled not reported	<input type="checkbox"/>	Poor reporting

**Exclusion rate from the analysis in exposed and not exposed**

Exclusion from the analyses was not reported separately for exposed and nonexposed	<input type="checkbox"/>	Poor reporting
Reasons to exclude from the analyses differ for exposed and not exposed	<input type="checkbox"/>	Major flaw

**Address Bias****Sampling bias is addressed in the analysis. (Mark one best (\*) and all applicable responses)**

Not reported	<input type="checkbox"/>	Poor reporting
Not addressed in analysis	<input type="checkbox"/>	Minor flaw

**Internal Validity****Source to measure dependent variables (target, outcomes)**

Not reported	<input type="checkbox"/>	Poor reporting
Proxy reported (collected for the study)	<input type="checkbox"/>	Minor flaw
Obtained from medical records (mining of data collected for health care purposes)	<input type="checkbox"/>	Minor flaw
Obtained from administrative database (mining of data collected for health care purposes)	<input type="checkbox"/>	Minor flaw

**Dependent variable****Reference period, time of occurrence of the disease**

Reference period may be relevant but not included in definition of the outcome (define relevance specific for research question)	<input type="checkbox"/>	Minor flaw
Reference period different from recommended and not justified	<input type="checkbox"/>	Minor flaw

**Severity, degree of the symptoms of the chronic condition**

Severity is not relevant for the outcome	<input type="checkbox"/>	
Severity can be relevant but not assessed in the study	<input type="checkbox"/>	Major flaw

**Frequency of the symptoms (decide importance of frequency per day, week, or month specific for the nature of the outcomes)**

Frequency is not relevant for the outcome	<input type="checkbox"/>	
Frequency can be relevant but not assessed in the study	<input type="checkbox"/>	Minor flaw

**Validation of outcomes measurements**

No information about validation	<input type="checkbox"/>	Poor reporting
The authors reported inter-methods validation (one method vs. another)	<input type="checkbox"/>	Minor flaw
The authors did not validate the methods to measure dependent variables (nonvalid methods were obtained)	<input type="checkbox"/>	Major flaw

**Reliability of the estimates**

Not reported	<input type="checkbox"/>	Poor reporting
Intra-observer variability is reported with subjective judgment of reliability	<input type="checkbox"/>	Minor flaw
Inter-observer variability is reported with subjective judgment of reliability	<input type="checkbox"/>	Minor flaw

**Source to measure exposure (can be completed for more than one risk factor)**

Not reported	<input type="checkbox"/>	Poor reporting
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Proxy reported (collected for the study)	<input type="checkbox"/>	Minor flaw
Obtained from medical records (mining of data collected for health care purposes)	<input type="checkbox"/>	Minor flaw
Obtained from administrative database (mining of data collected for health care purposes)	<input type="checkbox"/>	Minor flaw

**Definition of the exposure (risk factors, independent variables)**

**Reference period/length of exposure)**

Reference period/length of exposure not relevant for the nature of exposure	<input type="checkbox"/>	
Reference period/length of exposure may be relevant but not included in definition of the exposure (define relevance specific for research question)	<input type="checkbox"/>	Minor flaw
Reference period/length of exposure different from recommended and not justified	<input type="checkbox"/>	Minor flaw

**Intensity/dose**

Intensity/dose is not relevant for exposure	<input type="checkbox"/>	
Intensity/dose can be relevant but not assessed in the study	<input type="checkbox"/>	Minor flaw

**Measure exposure**

**Measurements of the exposure (can be completed for more than one risk factor)**

Not reported	<input type="checkbox"/>	Poor reporting
The authors reported inter-methods validation (one method vs. another)	<input type="checkbox"/>	Minor flaw
The authors did not validate the methods to measure exposure (risk factors, independent variables)	<input type="checkbox"/>	Major flaw

**Reliability of exposure estimates**

Not reported	<input type="checkbox"/>	Poor reporting
Intra-observer variability is reported with subjective judgment of reliability	<input type="checkbox"/>	Minor flaw

**For case-control studies**

The authors did not state that the same methods were used to measure exposure risk factors, independent variable) in cases and controls	<input type="checkbox"/>	Minor flaw
The authors used different methods to measure exposure (risk factors, independent variable) in cases and controls	<input type="checkbox"/>	Major flaw

**Confounding factors or factors that can modify the association between risk factor and disease**

Not reported	<input type="checkbox"/>	Poor reporting
Major confounding factors/effect modifiers were not assessed	<input type="checkbox"/>	Major flaw
Major confounding factors /effect modifiers were assessed partially	<input type="checkbox"/>	Minor flaw

**Measure of confounding factors**

Not reported	<input type="checkbox"/>	Poor reporting
Unknown validity to measure confounding factors	<input type="checkbox"/>	Minor flaw
Non valid methods to measure confounding factors	<input type="checkbox"/>	Major flaw

**Followup****Loss of followup (acceptable important cut off can be specific for research question)**

Not reported	<input type="checkbox"/>	Poor reporting
Not applicable (no followup in the study)	<input type="checkbox"/>	
Loss of followup is larger than acceptable	<input type="checkbox"/>	

**For case-control studies**

Not reported	<input type="checkbox"/>	Poor reporting
% of nonresponse differed among cases and controls	<input type="checkbox"/>	Minor flaw
% of nonresponse reported for cases only	<input type="checkbox"/>	Minor flaw

**Masking of exposure status for investigators who measured dependent variables (outcomes)**

Not reported	<input type="checkbox"/>	Poor reporting
Was possible but not obtained	<input type="checkbox"/>	Minor flaw

**Statistical analysis**

Not reported	<input type="checkbox"/>	Poor reporting
The authors did not obtain methods to reduce bias	<input type="checkbox"/>	Major flaw

**Temporality (for cohort studies)****Assessment of temporality**

Not reported	<input type="checkbox"/>	Poor reporting
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**Appropriateness of statistical model to reduce research specific bias**

Strategies to reduce research specific bias not reported	<input type="checkbox"/>	Poor reporting
Authors did not use statistical models that may be the most appropriate according to the published literature (examples may include population stratification bias in case-control studies of genetic association, odds ratio in cohort studies of common diseases, missing data, large loss of followup)	<input type="checkbox"/>	Minor flaw
Authors did not justify choice of statistical models to reduce research specific bias	<input type="checkbox"/>	Minor flaw
Authors attempted to reduce bias in post hoc statistical adjustment	<input type="checkbox"/>	Minor flaw

**Dose response with exposure**

Not relevant for research question	<input type="checkbox"/>	
May be relevant but not reported	<input type="checkbox"/>	Poor reporting

**Reporting of tested hypothesis**

Unclear reporting of the estimates (unclear model, reference level, set of confounding factors...)	<input type="checkbox"/>	Poor reporting
Crude estimates	<input type="checkbox"/>	Major flaw
Incomplete selective reporting of the tested hypotheses (compared to aim and objectives)	<input type="checkbox"/>	Minor flaw
<b>Precision of the estimates</b>		
Numeric value of estimates not reported (p value only, significance or non significance only)	<input type="checkbox"/>	Minor flaw
Mean only reported without p value or variance	<input type="checkbox"/>	Poor reporting
<b>Sample size justification</b>		
Not reported	<input type="checkbox"/>	Poor reporting
Justification by authors is incomplete or inaccurate	<input type="checkbox"/>	Minor flaw
Post-hoc analyses	<input type="checkbox"/>	Minor flaw

**Quality Validity Report**  
(Access reports are generated based on responses above)

Item	Decision
Manuscript: _____	
Reviewer: _____	

**External Validity**

Not reported	<input type="checkbox"/> Require reporting
Major flaws	<input type="checkbox"/> 1. Require justification that flaws could not be avoided or bias cannot be reduced <input type="checkbox"/> 2. Reject manuscript
Minor flaws	<input type="checkbox"/> 1. Require justification that flaws could not be avoided or bias cannot be reduced <input type="checkbox"/> 2. Reject manuscript

**Internal Validity**

Not reported	<input type="checkbox"/> Require reporting
Major flaws	<input type="checkbox"/> 1. Require justification that flaws could not be avoided or bias cannot be reduced <input type="checkbox"/> 2. Reject manuscript
Minor flaws	<input type="checkbox"/> 1. Require justification that flaws could not be avoided or bias cannot be reduced <input type="checkbox"/> 2. Reject manuscript