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

Please define in the protocol specific for your research quality components:

1. **Define and justify target population** _____
   Define and justify population subgroups if applicable, race _____, gender _____, other _____
2. Define and justify exposure (risk factors) _____
3. **Response rate.** Justify acceptable response rate: _____ and rate that can be defined as a major flaw of the study _____ in the total sample and in race, gender, and other subgroups if applicable.
4. **Exclusion rate from the analysis** - define in the protocol ranges specific for your research _____ and rate that can be defined as a major flaw of the study _____ in the total sample and in race, gender, and other subgroups if applicable
5. **Source of measure outcomes. D**efine and justify minor flaws specific for the nature of the condition:

Sources	**Suggested minor flaws**
Self reported (collected for the study)	
Proxy reported (collected for the study)	Minor flaw
Objectively measured with diagnostic methods for the purpose of the study (independent on health care)	
Measured by interviewers for the study	
Obtained during clinical exam for the purpose of the study	
Obtained from medical records (mining of the data collected for health care purposes)	Minor flaw
Obtained from administrative database (mining of the data collected for health care purposes)	Minor flaw
Obtained from registries or administrative databases (collected for epidemiologic evaluation independent of health care)	
Other (please specify)	

1. **Reference period** (time of occurrence) in a definition of the outcome. Define and justify reference period specific for the nature of the outcomes _____
2. **Severity** (degree of the symptoms of the chronic disease) in a definition of the outcome. Define and justify severity is applicable for the nature of the outcomes _____
3. **Frequency of the symptoms of the chronic disease in a definition of the outcome. Define and justify** importance of frequency per day, week, or month specific for the nature of the disease _____
4. **Gold standard to measure the outcomes.** Define and justify gold standard (if known) to measure outcomes _____
5. **Reliability of the estimates.** Define and justify acceptable Intra-observer variability _____ and inter-observer reliability _____
6. **Source of measure exposure. D**efine and justify minor flaws specific for the nature of the condition:

Source	**Suggested minor flaw**
Self reported (collected for the study)	
Proxy reported (collected for the study)	Minor flaw
Objectively measured with diagnostic methods for the purpose of the study (independent on health care)	
Measured by interviewers for the study	
Obtained during clinical exam for the purpose of the study	
Obtained from medical records (mining of data collected for health care purposes)	Minor flaw
Obtained from administrative database (mining of data collected for health care purposes)	Minor flaw
Obtained from registries (collected for epidemiologic evaluation independent of health care)	
Other (please specify)	

Reference period (time of occurrence) in a definition of the Exposure. Define and justify reference period specific for the nature of exposure _____

Length of exposure when applicable in the definition/assessment of exposure. Define and justify a length of exposure that was established by consensus of the experts or in guidelines _____

Intensity/dose of exposure. Define and justify importance of dose specific for the nature of the exposure (list for each risk factor _____

Measure of exposure. Define and justify gold standards to measure risk factors:

Factor _____ known gold standard

Confounding factors or factors that can modify the association between risk factor and disease. Define and justify set of major confounding factors specific for the association of the interest _____

Measure of confounding factors. Define and justify gold standards to measure primary confounding factors.

Factor _____ known gold standard _____

Loss of followup. Define and justify acceptable cutoff for loss of followup _____

Appropriateness of statistical model to reduce research specific bias. Define and justify the most appropriate methods specific for research questions _____

Instructions about the survey forms in Access format:

(1) If you are using Office 2007, probably you'll see an "Option" button right above this window. Please click on the button and choose "Enable this context."
(2) For a questions ending with a Minor flaw symbols, please provide at least one response.
(3) When you are typing in a textbox, your input is not saved until you click on any other textbox or checkbox.
(4) You can exit the program at anytime, and then resume the survey later by selecting the same Article ID.
(5) Help is available by clicking on the word Help next to the item you see.
(6) Though a textbox for "Other (please specify)" shows only about 2 lines of text, it can contain more than 6,000 words. This is just like a small window to see a big world.

Descriptive

Journal of publication _____

Year of publication _____

Funding of study (Mark one best (*) and all applicable responses)

A	Not reported	Poor reporting
B	Industry	
C	Grant	
D	Combined industry + grant	
E	Other (please specify)	

Role of funding organization in data analysis and interpretations of the results (Mark all applicable responses):

A	Not reported	Poor reporting
B	Sponsoring organization participated in data analyses	
C	Other (specify)	
D	Sponsoring organization did not participate in data analyses and interpretation	

Conflict of interest (Mark all applicable responses):

A	Disclosure not reported	Poor reporting
B	Reported not having conflict of interest	
C	Reported having conflict of interest	
D	Other (specify)	

Country _____

Ethical approval of the study (Mark all applicable responses):

A	Not reported	Poor reporting
B	Study was approved by Ethical Committee	
C	Other (specify)	

Aim

Aim of the study. (Mark one best (*) and all applicable responses)

A	Aim was not stated	Poor reporting
B	Included association with risk factors in the general population	
C	Included association with risk factors in race subgroups	
D	Included association with risk factors in gender subgroups	
E	Included association with risk factors in other population subgroups (define: diseases, specific demographics, socio-economic, or legal status, access to health insurance...)	
F	Included association with risk factors without clear definition of the target population	Minor flaw
G	Other (please specify)	

Objectives

(Mark one best (*) and all applicable responses)

A	Not clear statement	Poor reporting
B	Estimation of the association with prevalence of chronic conditions	
C	Estimation of the association with incidence of chronic conditions	
D	Other (please specify)	

Design

Study Design (Mark one best (*) and all applicable responses)

A	Not clear statement about the study design	Poor reporting
B	Cross-sectional	
C	Cohort (prospective) study with concurrent controls	
D	Cohort (retrospective) study with concurrent controls	
E	Case-controlled (retrospective) study	
F	Cohort (prospective) study with historical controls	
G	Nested case-control	
H	Other (please specify)	

External Validity

Sampling of the subjects by investigators

General population based (Mark one best (*) and all applicable responses)

A	Not reported	Poor reporting
B	Random population based	
C	Nonrandom population based	
D	Random multistage population based	
E	Random stratified population based	
F	Random sampling restricted to geographic area	
G	Other sampling of the general population (please specify)	

Nongeneral population based sampling method (Mark one best (*) and all applicable responses)

A	Not reported	Poor reporting
B	Random	
C	Convenient	Minor flaw
D	Self selection	Minor flaw
E	Other (please specify)	

Nongeneral population-based sampling frame (Mark one best (*) and all applicable responses)

A	Not reported	
B	Sampling within nationally representative registries or databases	
C	Medical records	Major flaw
D	Insurance claims	Major flaw
E	Work place	Major flaw
F	Health care based (clinics, hospitals)	Major flaw
G	Proxy selection (parents, relatives, legal representatives, caretakers...)	
H	Other (please specify)	

For case-control studies. (Mark one best (*) and all applicable responses)

A	Sampling of controls are not clearly reported	Poor reporting
B	Sampling of controls from the sample population as cases	
C	Sampling of controls from different population as cases	Major flaw
D	Sampling of controls from health care related sources (out-clinic or in-clinics, health care claims)	Minor flaw
E	Sampling of controls from work-related sources	
F	Sampling of controls from multiple sources	
G	Other (please specify)	

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). (Mark one best (*) and all applicable responses)

A	No information about sampling bias	Poor reporting
B	Sampling bias was assessed by the authors - differences in study population vs. target population are reported	
C	The authors did not assess sampling bias	Minor flaw
D	The authors did not assess sampling bias but justified exclusion of the subjects from the sampling or analysis	
E	Other (please specify)	

Estimate bias

Response rate in total sample - define in the protocol ranges specific for research area. Please note that included ranges are simply illustrative; they need to be justified and vary with each systematic review. (Mark one best (*) and all applicable responses)

A	Not reported	Poor reporting
B	>40 %	
C	<10-20%	Major flaw
D	21-40%	
E	Other (please specify)	

Exclusion rate from the analysis in total sample (define in the protocol acceptable ranges specific for research question). (Mark one best (*) and all applicable responses)

A	Not reported	Poor reporting
B	>10%	Major flaw
C	0-5%	
D	6-10%	
E	Other (specify)	

Exclusion rate from the analysis in exposed and not exposed (Mark one best (*) and all applicable responses)

A	Exclusion from the analyses was not reported separately for exposed and nonexposed	Poor reporting
B	Reasons to exclude from the analyses were the same for exposed and not exposed	
C	Reasons to exclude from the analyses differ for exposed and not exposed	Major flaw
D	Specify reasons for exclusion	

Address Bias

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

A	Not reported	Poor reporting
B	Weighting of the estimates by probability of selection	
C	Weighting of the estimates by nonresponse adjustment within sampling subgroups	
D	Post-stratification by age	
E	Post-stratification by sex	
F	Post-stratification by race	
G	Not addressed in analysis	Minor flaw
H	Other (please specify)	

Subject flow (define in the protocol the acceptable ranges specific for the area of research) (Mark one best (*) and all applicable responses)

A	Not applicable for study design	
B	Number of screened	
C	Not reported	Poor reporting
D	Number eligible	
E	Not reported	Poor reporting
F	Number enrolled	
G	Not reported	Poor reporting

Calculations with query Recruitment fractions (Insert calculated number, %)	
A	Eligibility fraction: # eligible / # screened
C	Enrollment fraction: # enrolled / # eligible
E	Recruitment fraction: # enrolled / # screened
G	Number needed to screen: 1 / recruitment fraction

Internal Validity

Source to measure dependent variables (target, outcomes) (define in the protocol flaws specific for the nature of the condition). (Mark one best (*) and all applicable responses)

A	Not reported	Poor reporting
B	Self reported (collected for the study)	
C	Proxy reported (collected for the study)	Minor flaw
D	Objectively measured with diagnostic methods for the purpose of the study (independent on health care)	
E	Measured by interviewers for the study	
F	Obtained during clinical exam for the purpose of the study	
G	Obtained from medical records (mining of data collected for health care purposes)	Minor flaw
H	Obtained from administrative database (mining of data collected for health care purposes)	Minor flaw
I	Obtained from registries (collected for epidemiologic evaluation independent of health care)	
J	Other-please specify	

Dependent variable

Reference period, time of occurrence of the disease (define reference period specific for the nature of the outcomes). (Mark one best (*) and all applicable responses)

A	Reference period not relevant for the nature of the outcome	
B	Reference period may be relevant but not included in definition of the outcome (define relevance specific for research question)	Minor flaw
C	Reference period recommended by the CDC or guidelines (12 months for chronic diseases) is included in definition of the outcome	
D	Reference period different from recommended is justified and included in the definition	
E	Reference period different from recommended and not justified	Minor flaw
F	Other (please specify)	

Severity, degree of the symptoms of the chronic condition (define importance of severity specific for the nature of the outcomes). (Mark one best (*) and all applicable responses)

A	Severity is not relevant for the outcome	
B	Severity can be relevant but not assessed in the study	Major flaw
C	Definition of the outcomes included severity of conditions	
D	Other (please specify)	

Frequency of the symptoms (define importance of frequency per day, week, or month specific for the nature of the outcomes). (Mark one best (*) and all applicable responses)

A	Frequency is not relevant for the outcome	
B	Frequency can be relevant but not assessed in the study	Minor flaw
C	Definition of the outcomes included frequency of diagnostic criterion of chronic conditions	
D	Other (please specify)	

Validation (Mark one best (*) and all applicable responses)

A	No information about validation	Poor reporting
B	Variables were measured using known "gold standard" (define specific for the outcomes)	
C	Methods to measure outcomes were validated with gold standard	
D	The authors reported inter-methods validation (one method vs. another)	Minor flaw
E	The authors did not validate the methods to measure dependent variables (nonvalid methods were obtained)	Major flaw
F	The authors justified validity of the used methods from previously published research	
G	Other (please specify)	

Reliability of the estimates (Mark one best (*) and all applicable responses)

A	Not reported	Poor reporting
B	Reliability assumed acceptable according to previous published analyses (medical coding, insurance claims)	
C	Intra-observer variability is within acceptable for the outcome standards (define acceptable variability specific for the nature of the outcome)	
D	Intra-observer variability is reported with subjective judgment of reliability	Minor flaw
E	Inter-observer variability is within acceptable for the outcome standards (define acceptable variability specific for the nature of the outcome)	
F	Inter-observer variability is reported with subjective judgment of reliability	Minor flaw
G	Other (please specify)	

When one study reported several risk factors with different probability of bias/error among tested hypotheses, please decide if quality assessment is needed for each risk factor.
If yes, abstract information adding as many risk factors as you need. Define risk factor or list risk factors for which quality assessment would be the same.
Define risk factor or list risk factors for which quality assessment would be the same:

Source to measure exposure
Hypothesis specific: complete for each risk factor. Source to measure exposure (risk factors, independent variables, input). (Mark one best (*) and all applicable responses)

A	Not reported	Poor reporting
B	Self reported (collected for the study)	
C	Proxy reported (collected for the study)	Minor flaw
D	Objectively measured with diagnostic methods for the purpose of the study (independent on health care)	
E	Measured by interviewers for the study	
F	Obtained during clinical exam for the purpose of the study	
G	Obtained from medical records (mining of data collected for health care purposes)	Minor flaw
H	Obtained from administrative database (mining of data collected for health care purposes)	Minor flaw
I	Obtained from registries (collected for epidemiologic evaluation independent of health care)	
J	Other (please specify)	

Define exposure
Definition of the exposure (risk factors, independent variables) (specific for research questions)
Hypothesis specific: complete for each risk factor.
Reference period/length of exposure (define reference period specific for the nature of the exposure risk factors, independent variables). (Mark one best (*) and all applicable responses)

A	Reference period/length of exposure not relevant for the nature of exposure	
B	Reference period/length of exposure may be relevant but not included in definition of the exposure (define relevance specific for research question)	Minor flaw
C	Reference period/length of exposure recommended by guidelines is included in definition of exposure	
D	Reference period/length of exposure different from recommended is justified and included in the definition	
E	Reference period/length of exposure different from recommended and not justified	Minor flaw
F	Other (please specify)	

Hypothesis specific: complete for each risk factor. Intensity/dose (define importance of dose specific for the nature of the exposure (risk factors, independent variables). (Mark one best (*) and all applicable responses)

A	Intensity/dose is not relevant for exposure	
B	Intensity/dose can be relevant but not assessed in the study	Minor flaw
C	Definition of the exposure (risk factors, independent variables) included intensity/dose	
D	Other (please specify)	

Measure exposure
Measurements of the exposure (risk factors, independent variables).

Hypothesis specific: complete for each risk factor. Validation. (Mark one best (*) and all applicable responses)

A	Not reported	Poor reporting
B	Exposure (risk factors, independent variables) were measured using known "gold standard" (define specific for the exposure)	
C	Methods to measure exposure (risk factors, independent variables) were validated with gold standard	
D	The authors reported inter-methods validation (one method vs. another)	Minor flaw
E	The authors did not validate the methods to measure exposure (risk factors, independent variables)	Major flaw
F	The authors justified validity of the used methods from previously published research	
G	Other (please specify)	

Hypothesis specific: complete for each risk factor. Reliability of the estimates. (Mark one best (*) and all applicable responses)

A	Not reported	Poor reporting
B	Reliability assumed acceptable according to previous published analyses	
C	Intra-observer variability is acceptable for exposure standards (define acceptable variability specific for the nature of exposure)	
D	Intra-observer variability is reported with subjective judgment of reliability	Minor flaw
E	Inter-observer variability is within acceptable for exposure standards (define acceptable variability specific for the nature of exposure)	
F	Inter-observer variability is reported with subjective judgment of reliability	
G	Other (please specify)	

Design specific. For case-control studies. (Mark one best (*) and all applicable responses)

A	The same methods were used to measure exposure risk factors, independent variable) in cases and controls	
B	The authors did not state that the same methods were used to measure exposure risk factors, independent variable) in cases and controls	Minor flaw
C	The authors used different methods to measure exposure (risk factors, independent variable) in cases and controls	Major flaw
D	Other (please specify)	

Confounding factors or factors that can modify the association between risk factor and disease (define in the protocol the primary confounding factors specific for the association of the interest). Mark one best (*) and all applicable responses

A	Not reported	Poor reporting
B	Major confounding factors/effect modifiers were not assessed	Major flaw
C	Major confounding factors /effect modifiers were assessed partially	Minor flaw
D	Major confounding factors/effect modifiers were assessed (known sets of confounders specific for research questions)	
E	Other (please specify)	

Measure of confounding factors (define the protocol gold standards to measure primary confounding factors specific for the research question). (Mark one best (*) and all applicable responses)

A	Not reported	Poor reporting
B	Valid measurements of major confounding factors	
C	Unknown validity to measure confounding factors	Minor flaw
D	Non valid methods to measure confounding factors	Major flaw
E	The authors justified validity of the used methods from previously published research	
F	Other (please specify)	

Followup

Loss of followup (define acceptable important cut off specific for research question). (Mark one best (*) and all applicable responses)

A	Not reported
B	% in total sample
C	% among exposed and not exposed
D	Not applicable (no followup in the study)
E	Loss of followup is larger than acceptable
F	Other (please specify)

Design specific for case-control studies. (Mark one best (*) and all applicable responses)

A	Not reported	Poor reporting
B	% of nonresponse among cases the same as for controls	
C	% of nonresponse differed among cases and controls	Minor flaw
D	% of nonresponse reported for cases only	Minor flaw
E	Other (please specify)	

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

A	Not reported	Poor reporting
B	Was stated	
C	Was not possible	
D	Was possible but not obtained	Minor flaw
E	Was stated and assessed	
F	Other (please specify)	

Statistics
Statistical analysis. (Mark one best (*) and all applicable responses)

A	Not reported	Poor reporting
B	Standardization	
C	Matching	
D	Adjustment in multivariate model	
E	Stratification	
F	Propensity scoring	
G	The authors did not obtain methods to reduce bias	Major flaw
H	Several methods to reduce bias	
I	Other methods were justified and obtained to reduce bias (please specify)	

Temporality
For cohort studies.
Design and hypothesis specific. Assessment of temporality. (Mark one best (*) and all applicable responses)

A	Not reported	Poor reporting
B	Demonstration that exposure preceded the outcome (the disease of interest was not present at start of study)	
C	Other (specify)	

Appropriateness

Appropriateness of statistical model to reduce research specific bias (define in the protocol the most appropriate methods specific for research questions). (Mark one best (*) and all applicable responses)

A	Strategies to reduce research specific bias not reported	Poor reporting
B	Authors justified using appropriate statistical models to reduce research specific bias	
C	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)	Minor flaw
D	Authors did not justify choice of statistical models to reduce research specific bias	Minor flaw
E	Authors attempted to reduce bias in post hoc statistical adjustment	Minor flaw
F	Other (please specify)	

Dose response

Hypothesis specific: complete for each risk factor. Dose response with exposure. (Mark one best (*) and all applicable responses)

A	Not relevant for research question	
B	May be relevant but not reported	Poor reporting
C	Reported as significant	
D	Reported as nonsignificant	
E	Other (please specify)	

Report

Hypothesis specific. Reporting of tested hypothesis. (Mark one best (*) and all applicable responses)

A	Unclear reporting of the estimates (unclear model, reference level, set of confounding factors...)	Poor reporting
B	Crude estimates	Major flaw if C is not marked
C	Authors reported estimates of primary and secondary hypotheses adjusted for confidential sources of bias	
D	Incomplete selective reporting of the tested hypotheses (compared to aim and objectives)	Minor flaw
E	Other (please specify)	

Precision

Hypothesis specific. Precision of the estimates (Mark one best (*) and all applicable responses)

A	Mean with 95% CI reported	
B	Mean and standard error of estimates reported	
C	Numeric value of estimates not reported (p value only, significance or non significance only)	Minor flaw
D	Mean only reported without p value or variance	Poor reporting
E	Other (please specify)	

Sample Size
Sample size justification. (Mark one best (*) and all applicable responses)

A	Not reported	Poor reporting
B	Justified for primary outcome	
C	Justified for secondary outcomes	
D	Justification by authors is incomplete or inaccurate	Minor flaw
E	Post-hoc analyses	Minor flaw
F	Other (please specify)	

Example of Quality Validity Report

Item	Issue
Article: _____	
Evaluator: _____	
External Validity	
Not reported	
Estimation of sampling bias: Addressing sampling bias	Not reported
Estimation of sampling bias: Response rate in total sample	Not reported
Estimation of sampling bias: Subject flow	Number of eligible not reported
Assessment of sampling bias	No information about sampling bias
Internal Validity	
Major	
Measurement of dependent variable (target=outcomes): Validation	Did not validate the methods to measure dependent variables (nonvalid methods were obtained)
Minor	
Measure of confounding factors	Unknown validity to measure confounding factors
Not reported	
Masking of exposure status for investigators who measured dependent variables (outcomes)	Not reported
Measurements of dependent variable (target=outcomes): Reliability	Not reported
Article: _____	
Evaluator: _____	
External Validity	
Minor	
Sampling: For case control study	Sampling of controls from health care related sources (out clinic or in clinics, health care claims)
Not reported	
Estimation of sampling bias: Subject flow	Number of screened not reported
Estimation of sampling bias: Subject flow	Number of enrolled not reported
Estimation of sampling bias: Subject flow	Number of eligible not reported
Estimation of sampling bias: Response rate in total sample	Not reported
Estimation of sampling bias: Exclusion rate from analysis	Not reported
Sampling: Nongeneral population based sampling method	Not reported
Assessment of sampling bias	No information about sampling bias
Estimation of sampling bias: Addressing sampling bias	Not reported
Internal Validity	
Minor	
Measure of confounding factors	Unknown validity to measure confounding factors
Definition of the dependent variable (target=outcome): Reference period	May be relevant but not included in definition of the outcome
Not reported	

Loss of followup	Not reported
Masking of exposure status for investigators who measured dependent variables (outcomes)	Not reported
Article: _____	
Evaluator: _____	
External Validity	
Not reported	
Estimation of sampling bias: Subject flow	Number of eligible not reported
Estimation of sampling bias: Subject flow	Number of screened not reported
Estimation of sampling bias: Exclusion rate from the analysis	Not reported
Estimation of sampling bias: Addressing sampling bias	Not reported
Assessment of sampling bias	No information about sampling bias
Sampling: General population based	Not reported
Internal Validity	
Minor	
Confounding factors or the factors that can modify the association: risk factor and disease	Major confounding factors/effect modifiers were assessed partially
For cohort study: Appropriateness of statistical model to reduce research specific bias	Did not justify choice of statistical models to reduce research specific bias
Not reported	
Measurements of dependent variable (target=outcomes): Validation	No information about validation
Loss of followup	Not reported
Masking of exposure status for investigators who measured dependent variables (outcomes)	Not reported
Measure of confounding factors	Not reported
Measurements of dependent variable (target=outcomes): Reliability	Not reported