Methodological Evaluation of Observational REsearch (MORE)—Observational Studies of Incidence or Prevalence of Chronic Diseases

Please define 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. **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.
3. **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.
4. **Source of measure incidence/prevalence of chronic diseases. Define 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 of 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 if applicable for the nature of the outcomes _____
3. **Frequency of the symptoms of the chronic disease in definition of the outcome. Define and justify** importance of frequency per day, week, or month specific for the nature of the disease _____
4. **Dependent variable (outcomes) in subpopulations.** Define and justify the major flaw in assessment of the variables in subpopulations, if applicable _____
5. **Gold standard to measure the outcomes.** Define and justify gold standard (if known) to measure outcomes _____
6. **Reliability of the estimates.** Define and justify acceptable intra-observer variability _____ and inter-observer reliability _____

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 symbol, 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

Article ID (file name) _____

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 (specify)	

Role of funding organization in data analysis and interpretations of the results (mark one best (*) and all applicable responses):

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

Conflict of interest (Mark one best (*) and all applicable responses):

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

Country _____

Ethical approval of the study (Mark one best (*) and all applicable responses):

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

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

A	Aim was not stated	Poor reporting
B	Included prevalence estimation in the general population	
C	Included prevalence estimation in racial subgroups	
D	Included prevalence estimation in sex subgroups	
E	Included prevalence estimation in other population subgroups (define)	
F	Included prevalence estimation without clear target population	Minor flaw
G	Included Incidence estimation in the general population	
H	Included Incidence estimation in racial subgroups	
I	Included Incidence estimation in sex subgroups	
J	Included Incidence estimation in other population subgroups (define)	
K	Included Incidence estimation without clear target population	Minor flaw

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

A	Not clear statement	Poor reporting
B	Cross-sectional	
C	Retrospective	
D	Prospective	
E	Other (please specify)	

External Validity

Sampling of the subjects by the investigators. General population based (Mark one best (*) and all applicable responses):

A	Not reported	Poor reporting
B	Random population based	
C	Non-random population based	
D	Random multistage population based	
E	Random stratified population based	
F	Random sampling restricted to geographic area (minor flaw if the aim was to examine incidence/prevalence in the general population without place restrictions)	Minor flaw
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 (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, care takers...)	
H	Other (please specify)	

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 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	>60%	
C	<40%	Major flaw
D	40-60%	
E	Other (specify)	

Response rate in race subgroups (if applicable): define the protocol ranges specific for the research area. Please note that included ranges are simply illustrative; they need to be justified and vary with each systematic review.

A	Not reported	Poor reporting
B	>60%	
C	<40%	Major flaw
D	40-60%	
E	Other (specify)	

Response rate in gender subgroups (if applicable)—define 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.

A	Not reported	Poor reporting
B	>60%	
C	<40%	Major flaw
D	40-60%	
E	Other (specify)	

One study could examine incidence or prevalence in the total sample and in population subgroups with different probability of bias/error. Please decide if quality assessment is needed for each population subgroup.
If yes, abstract information adding evaluation tables for as many subgroups as you need. Specify definition of each subgroup.

Response rate in other subgroups - define 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.

A	Not reported	Poor reporting
B	>60%	
C	<40%	Major flaw
D	40-60%	
E	Other (specify)	

Exclusion rate from the analysis - define 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.

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

Exclusion rate in subgroups (if applicable):

A	Not reported	Poor reporting
B	>10%	Major flaw
C	0-5%	
D	6-10%	
E	Different exclusion rate in evaluated subgroups (specify)	

Address Bias

Sampling bias is addressed in the analysis:

A	Not reported	Poor reporting
B	Weighting of the estimates by probability of selection	
C	Weighting of the estimates by non-response 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 specify0	

Subject flow (define in the protocol the acceptable ranges specific for the area of research):

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

Recruitment fractions (automatically calculated):

Eligibility fraction: # eligible / # screened
Enrollment fraction: # enrolled / # eligible
Recruitment fraction: # enrolled / # screened
Number needed to screen: 1 / recruitment fraction

Internal Validity

Source of measure incidence/prevalence of chronic diseases (dependent variables) (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 the data collected for health care purposes)	Minor flaw
H	Obtained from administrative database (mining of the data collected for health care purposes)	Minor flaw
I	Obtained from registries or administrative databases (collected for epidemiologic evaluation independent of health care)	
J	Other (please specify)	

Reference period (time of occurrence) (defined in the protocol 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 disease) (define importance of severity specific for the nature of the disease). (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 of the chronic disease (define in the protocol importance of frequency per day, week, or month specific for the nature of the disease). (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)	

Dependent variable (outcomes) in subpopulations (if applicable). (Mark applicable responses)

A	Measurements of the outcomes in subpopulations were not clarified	Poor reporting
B	The same methods were used to measure outcome in the total sample and in subgroups	
C	Outcomes in subpopulations were measured differently (define in the protocol the major flaw in assessment of the variables in subpopulations in applicable)	Minor flaw
D	Other (please specify)	

Reporting of prevalence: Type (Mark the best responses)

A	Not clear	Poor reporting
B	Point prevalence	Minor flaw
C	Period prevalence	
D	Other (please specify)	

Precision of estimate (error, 95% CI). (Mark one best (*) and all applicable responses)

A	Omitted	Poor reporting
B	Reported	
C	Other (please specify)	

Prevalence in total sample. (Mark the best responses):

A	Crude prevalence in total sample	Minor flaw
B	Age adjusted prevalence in total sample	
C	Other (specify)	

Prevalence in population subgroup (define relevant subgroups specific for research question). (Mark one best (*) and all applicable responses)

A	Stated as aim of the study but nor reported	Poor reporting
B	Crude prevalence in age subgroups	
C	Crude prevalence in race groups	Minor flaw
D	Crude prevalence in gender groups	Minor flaw
E	Crude prevalence other subgroups	Minor flaw
F	Age adjusted prevalence in race subpopulations	
G	Age adjusted prevalence in gender subpopulations	
H	Standardized estimation of prevalence by age and gender	
I	Age adjusted prevalence in other subgroups	
J	Other (please specify)	

Reporting of Incidence: Incidence Type. (Mark one best (*) and all applicable responses)

A	Not clear	Poor reporting
B	Cumulative incidence	
C	Incidence rate	
D	Other (specify)	

Precision of estimation (error, 95% CI). (Mark one best (*) and all applicable responses)

A	Omitted	Poor reporting
B	Reported	
C	Other (specify)	

Incidence in total sample. (Mark one best (*) and all applicable responses)

A	Crude incidence in total sample	Minor flaw
B	Age adjusted incidence in total sample	
C	Other (specify)	

Incidence in population subgroups (define relevant subgroups specific for research question). Mark one best (*) and all applicable responses

A	Stated in the aim of the study but not reported	Poor reporting
B	Crude incidence in age subgroups	
C	Crude incidence in race groups	Minor flaw
D	Crude incidence in gender groups	Minor flaw
E	Age adjusted incidence in race subpopulations	
F	Age adjusted incidence in gender subpopulations	
G	Standardized estimation of incidence by age and gender	
H	Crude incidence in other subgroups	Minor flaw
I	Age adjusted incidence in other subgroups	
J	Other (specify)	

Example of Quality Validity Report

Item	Issue
Article: _____	
Evaluator: _____	
External Validity	
Not reported	
Estimation of sampling bias: Exclusion rate from the analysis	Not reported
Estimation of sampling bias: Response rate in total sample	Not reported
Sampling: Assessment of sampling bias	No information about sampling bias
Sampling: Sampling method, Not general population based	Not reported
Estimation of sampling bias: Addressing sampling bias	Not reported
Internal Validity	
Minor	
Definition of incidence/prevalence: Frequency of symptoms	Can be relevant but not assessed in the study
Not Reported	
Measurements of incidence/prevalence: Reliability	Not reported
Article: _____	
Evaluator: _____	
External Validity	
Major	
Estimation of sampling bias: Exclusion rate from the analysis	>10%
Sampling: Sampling method: Nongeneral population based	Health care based (clinics, hospitals)
Minor	
Sampling: Sampling method: Nongeneral population based	Convenient
Not reported	
Estimation of sampling bias: Subject flow	Number of screened not reported
Estimation of sampling bias: Addressing sampling bias	Not reported
Sampling: Assessment of sampling bias	No information about sampling bias
Article: _____	
Evaluator: _____	
External Validity	
Major	
Sampling: Sampling frame: Nongeneral population based	Health care based (clinics, hospitals)
Minor	
Sampling: Sampling method: Nongeneral population based	Convenient
Not reported	
Estimation of sampling bias: Addressing sampling bias	Not reported
Estimation of sampling bias: Exclusion rate from the analysis	Not reported
Estimation of sampling bias: Subject flow	Number of eligible not reported
Estimation of sampling bias: Subject flow	Number of screened not reported
Sampling: Assessment of sampling bias	No information about sampling bias
Internal Validity	
Not Reported	
Measurements of incidence/prevalence: Reliability	Not reported