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

Stopping Rules

External Validity

Sampling of the subjects by investigators
Nongeneral population-based sampling frame

Not reported		Level C
Medical records	Major flaw	Level A
Insurance claims	Major flaw	Level A
Work place	Major flaw	Level A
Health care based (clinics, hospitals)	Major flaw	Level A

For case-control studies

Sampling of controls are not clearly reported	Poor reporting	Level C
Sampling of controls from different population as cases	Major flaw	Level A
Sampling of controls from health care related sources (out-clinic or in-clinics, health care claims)	Minor flaw	Level C

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

Not reported	Poor reporting	Level C
<40 (or less than cut off specific for the target population) %	Major flaw	Level A

Response rate in race or other subgroups (if applicable)

Not reported	Poor reporting	Level C
<40 (or less than cut off specific for the target population) %	Major flaw	Level A

Exclusion rate from the analysis

Not reported	Poor reporting	Level C
>10%	Major flaw	Level A

Exclusion rate in subgroups (if applicable)		
Not reported	Poor reporting	Level C
>10%	Major flaw	Level A

Exclusion rate from the analysis in exposed and not exposed		
Exclusion from the analyses was not reported separately for exposed and nonexposed	Poor reporting	Level C
Reasons to exclude from the analyses differ for exposed and not exposed	Major flaw	Level C

Internal Validity

Source to measure dependent variables (target, outcomes)

Not reported	Poor reporting	Level C
Proxy reported (collected for the study)	Minor flaw	Level C
Obtained from medical records (mining of data collected for health care purposes)	Minor flaw	Level C
Obtained from administrative database (mining of data collected for health care purposes)	Minor flaw	Level C

Severity, degree of the symptoms of the chronic condition

Severity can be relevant but not assessed in the study	Major flaw	Level A

Validation of outcomes measurements

No information about validation	Poor reporting	Level C
The authors did not validate the methods to measure dependent variables (nonvalid methods were obtained)	Major flaw	Level A

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

Not reported	Poor reporting	Level C
Proxy reported (collected for the study)	Minor flaw	Level C
Obtained from medical records (mining of data collected for health care purposes)	Minor flaw	Level C
Obtained from administrative database (mining of data collected for health care purposes)	Minor flaw	Level C

Measure exposure

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

Not reported	Poor reporting	Level C
The authors reported inter-methods validation (one method vs. another)	Minor flaw	Level C
The authors did not validate the methods to measure exposure (risk factors, independent variables)	Major flaw	Level A

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	Minor flaw	Level C
The authors used different methods to measure exposure (risk factors, independent variable) in cases and controls	Major flaw	Level A

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

Not reported	Poor reporting	Level C
Major confounding factors/effect modifiers were not assessed	Major flaw	Level A
Major confounding factors /effect modifiers were assessed partially	Minor flaw	Level C

Statistical analysis

Not reported	Poor reporting	Level C
The authors did not obtain methods to reduce bias	Major flaw	Level A

Appropriateness of statistical model to reduce research specific bias

Strategies to reduce research specific bias not reported	Poor reporting	Level 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	Level C
Authors did not justify choice of statistical models to reduce research specific bias	Minor flaw	Level C
Authors attempted to reduce bias in post hoc statistical adjustment	Minor flaw	Level C

Reporting of tested hypothesis

Unclear reporting of the estimates (unclear model, reference level, set of confounding factors)	Poor reporting	Level C
Crude estimates	Major flaw	Level A
Incomplete selective reporting of the tested hypotheses (compared to aim and objectives)	Minor flaw	Level C