COHORT STUDIES QUALITY ASSESSMENT TOOL (RISK FACTORS)

(Adapted from the Newcastle-Ottawa tool for QA of clinical cohort studies for use in the Prostate Cancer Foundation of Australia and Cancer Council Australia auspiced - *Development of Clinical Practice Guidelines for PSA Testing and Early Management of Test-Detected Prostate Cancer*)

Bias in selection of participants into study

Selection of the exposed and non-exposed cohorts

1. Drawn from the same population (low risk)
2. Drawn from different populations but unlikely to introduce bias (moderate risk)
3. Drawn from different populations and likely to introduce bias OR insufficient information to tell (high risk)

Bias due to error in exposure measurement

Measurement of exposure

1. Objective measurements from pre-existing records or baseline[1] physical or biological assessment blind to outcome status (low risk)
2. Objective measurements from pre-existing records or baseline[1] physical or biological assessment not blind to outcome status, OR structured interview (moderate risk)
3. Self-administered questionnaire OR insufficient information to tell (high risk)

Bias due to error in outcome measurement

Measurement of outcome

1. Outcome measurement unlikely to be influenced by exposure (low risk)
2. Objective outcome measurement possibly influenced by exposure (moderate risk)
3. Objective outcome measurement probably influenced by exposure OR self-reported outcome OR insufficient information to tell (high risk)

Was outcome of interest absent at the time to which the exposure refers?

1. Yes (low risk)
2. No but outcome unlikely to affect exposure measurement (moderate risk
3. No and outcome likely to affect exposure measurement OR insufficient information to tell (high risk)

Was follow-up long enough for outcome to occur as a consequence of measured exposure? (Requires prior specification of a sufficient follow-up period)

1. Yes (low risk)
2. No OR insufficient information to tell (high risk)

[1] Existing at or before baseline, where baseline is the time at which a participant is recorded to have entered the cohort or, if obtained after baseline, before onset of symptoms of the outcome or any likely effect of the developing outcome on the exposure

Bias due to non-participation

Participation rate

1. Participation rate in exposed cohort is ≤10 percentage points different from non-exposed cohort OR exposed and non-exposed are from the same cohort (low risk)
2. Participation rate in exposed cohort is >10 percentage points but <20 percentage points different from non-exposed cohort (moderate risk)
3. Participation rate in exposed cohort ≥20 percentage points different from non-exposed cohort OR insufficient information to tell (high risk)

Bias due to missing data

Completeness of follow-up

1. Active or passive follow-up of participants with methods for ascertainment of outcome and death clearly described AND with methods for ascertainment of emigration from population-at-risk clearly described or censoring at date of last follow-up OR there is a plausible estimate of >90% follow-up (low risk)
2. Active or passive follow-up with methods for ascertainment of outcome, death and emigration from population-at-risk not clearly described OR there is a plausible estimate of 70 – 90% follow-up (moderate risk)
3. Active or passive follow-up with methods for ascertainment of one or more of outcome, death or emigration not described OR there was probably <70% follow-up OR insufficient information to tell (high risk)

Accuracy of dates of outcome or censoring

1. Dates of outcome or censoring ascertained to within one year (low risk)
2. One or more of dates of outcome or censoring not ascertained to within one year OR insufficient information to tell (moderate risk)

Difference in follow-up between exposed and non-exposed

1. Follow-up methods are the same and likely to achieve the same completeness of follow-up in exposed and unexposed participants (low risk)
2. Completeness of follow-up in exposed and unexposed participants is unlikely to be the same but difference between the two is, or would be likely to be, small (<10%) (moderate risk)
3. Completeness of follow-up in exposed and unexposed participants is very unlikely to be the same and difference between the two is, or is likely to be, large (≥10%) OR insufficient information to tell (high risk)

Difference in missing data for exposure between those with or without the outcome

1. Difference in missing data for exposure <10 percentage points (low risk)
2. Difference in missing data for exposure ≥10 to <20 percentage points (moderate risk)
3. Difference in missing data for exposure ≥20 percentage points (high risk) OR insufficient information to tell (high risk)

Bias due to confounding

Comparability of exposed and non-exposed cohorts with respect to potentially important confounding variables (Requires prior specification of potentially important confounders)

1. Age and other potentially important confounders measured and controlled by design or in analysis (low risk)
2. Age and some but not all other potentially important confounders controlled by design or in analysis (moderate risk)
3. No potentially important confounders or only age controlled by design or in analysis OR insufficient information to tell (high risk)

Analysis bias

Covariates are appropriately included in statistical analysis models

1. Variables measuring the same underlying concept or lying in the same causal pathway ARE NOT included together as covariates in statistical analysis models (low risk)
2. Variables measuring the same underlying concept or lying in the same causal pathway ARE included together as covariates in statistical analysis models OR insufficient information to tell (high risk)

Overall rating

High risk of bias – high risk of bias in any domain

Moderate risk of bias – moderate or low risk of bias in all domains, no high risk domains

Low risk of bias – all domains low risk of bias, no moderate or high risk domains