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Bias Classification Tool – Quality Assessment

Bias	NR	Minimal	Low	Moderate	High
Selection	☐	☐ Consectutive unselected population ☐ Sample selected from general population rather than a select group ☐ Eligibility criteria explained ☐ Rational for case and control selection explained ☐ Follow-up or assessment time explained	☐ Sample selected from large population but selection criteria not defined ☐ A select group of population (based on race, ethnicity, residence, etc.) studied	☐ Sample selection ambiguous but sample may be representative ☐ Eligibility criteria not explained ☐ Rationale for cases and controls not explained ☐ Follow-up or assessment time not explained	☐ Sample selection ambiguous and sample likely not representative ☐ Comparative groups differ in baseline characteristics ☐ A very select population studied making it difficult to generalise findings
Exposure	☐	☐ Direct questioning (interview) or completion of survey by mother at the time of exposure or close to the time of exposure ☐ Direct measurment of exposure (laboratory) ☐ Exposure from the chart	☐ Assessment of exposure from a dataset ☐ Indirect assessment (postal survey, mailed questionnaire) ☐ Recall <1 year after birth	☐ Recall 1-5 years after birth ☐ Extrapolating data from population exposure sample (with some assumptions) and not direct assessment at any time	☐ Recall >5 years after birth ☐ Indirect method of assessment (obtaining data from others and not from mother or father)
Outcome	☐	☐ Assessment from hospital record, birth certificate or from direct questionion of mothers about outcomes	☐ Assessment from administrative database	☐ Assessment from “close-ended” questions (Did you have a stillbirth or miscarriage?)	☐ Assessment from non-validated sources or generic estimate from overall population
Confounding	☐	☐ Assessed for common confounders	☐ Only certain confounders assessed	☐ Not assessed for confounders	
Analytical	☐	☐ Analyses appropriate for type of sample (if matched: paired t test, McNemar) ☐ Analytical method accounted for sampling strategy in cross-sectional study ☐ Sample size calculation performed and adequate sample studied	☐ Analyses not accounting for common statistical adjustment (e.g. multiple analyses e.g. Bonferroni) when appropriate ☐ Sample size calculation not performed, but all available eligible patients studied ☐ Sample size calculated and reasons for not meeting sample size given	☐ Sample size estimation unclear or only sub-sample of eligible patients studied	☐ Analyses inappropriate for type of sample/study
Attrition	☐	☐ None or <10% attrition and reasons for loss of follow-up explained ☐ All subjects from initiation of study to final outcome assessment were accounted for	☐ <10% attrition AND reasons for loss of follow-up not explained ☐ 11-20% attrition, reasons for loss of follow-up explained	☐ 11-20% attrition but reasons for loss of follow-up not explained ☐ >20% attrition but reasons for loss of follow-up explained ☐ All subjects from initiation of study to final outcome assessment not accounted for	☐ >20% attrition, reasons for loss of follow-up not explained