Appendix 1: Risk of Bias Tool

Name of author(s): ___________________________ Year of publication: ___________________________

Name of paper/study: ________________________

This tool is designed to assess the risk of bias in population-based prevalence studies. Please read the additional notes for each item when initially using the tool. Note: If there is insufficient information in the article to permit a judgement for a particular item, please answer No (HIGH RISK) for that particular item.

| Risk of bias item                                                                 | Criteria for answers (please circle one option) | Additional notes and examples                                                                 |
|----------------------------------------------------------------------------------|-------------------------------------------------|-----------------------------------------------------------------------------------------------|
| **External Validity**                                                            |                                                 |                                                                                               |
| 1. Was the study’s target population a close representation of the national population? | • Yes (LOW RISK): The study’s target population was a close representation of the national population.  
• No (HIGH RISK): The study’s target population was clearly NOT representative of the national population. | The target population refers to the group of people or entities to which the results of the study will be generalised. Examples:  
• The study was a national health survey of people 15 years and over and the sample was drawn from a list that included all individuals in the population aged 15 years and over. The answer is: Yes (LOW RISK).  
• The study was conducted in one province only, and it is not clear if this was representative of the national population. The answer is: No (HIGH RISK).  
• The study was undertaken in one village only and it is clear this was not representative of the national population. The answer is: No (HIGH RISK). |
| 2. Was the sampling frame a true or close representation of the target population? | • Yes (LOW RISK): The sampling frame was a true or close representation of the target population.  
• No (HIGH RISK): The sampling frame was NOT a true or close representation of the target population. | The sampling frame is a list of the sampling units in the target population and the study sample is drawn from this list. Examples:  
• The sampling frame was a list of almost every individual within the target population. The answer is: Yes (LOW RISK).  
• The cluster sampling method was used and the sample of clusters/villages was drawn from a list of all villages in the target population. The answer is: Yes (LOW RISK).  
• The sampling frame was a list of just one particular ethnic group within the overall target population, which comprised many groups. The answer is: No (HIGH RISK). |
| 3. Was some form of random selection used to select the sample, OR was a census undertaken? | • Yes (LOW RISK): A census was undertaken, OR, some form of random selection was used to select the sample (e.g. simple random sampling, stratified random sampling, cluster sampling, systematic sampling).  
• No (HIGH RISK): A census was NOT undertaken, AND some form of random selection was NOT used to select the sample. | A census collects information from every unit in the sampling frame. In a survey, only part of the sampling frame is sampled. In these instances, random selection of the sample helps minimise study bias. Examples:  
• The sample was selected using simple random sampling. The answer is: Yes (LOW RISK).  
• The target population was the village and every person in the village was sampled. The answer is: Yes (LOW RISK).  
• The nearest villages to the capital city were selected in order to save on the cost of fuel. The answer is: No (HIGH RISK). |
| 4. Was the likelihood of non-response bias minimal?                                | • Yes (LOW RISK): The response rate for the study was ≥75%, OR, an analysis was performed that showed no significant difference in relevant demographic characteristics between responders and non-responders  
• No (HIGH RISK): The response rate was <75%, and if any analysis comparing responders and non-responders was done, it showed a significant difference in relevant demographic characteristics between responders and non-responders. | Examples:  
• The response rate was 68%; however, the researchers did an analysis and found no significant difference between responders and non-responders in terms of age, sex, occupation and socio-economic status. The answer is: Yes (LOW RISK).  
• The response rate was 65% and the researchers did NOT carry out an analysis to compare relevant demographic characteristics between responders and non-responders. The answer is: No (HIGH RISK).  
• The response rate was 69% and the researchers did an analysis and found a significant difference in age, sex and socio-economic status between responders and non-responders. The answer is: No (HIGH RISK). |
## Internal Validity

| No. | Question                                                                 | Yes (LOW RISK)                                                                 | No (HIGH RISK)                                                                 |
|-----|--------------------------------------------------------------------------|-------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| 5.  | Were data collected directly from the subjects (as opposed to a proxy)?  | All data were collected directly from the subjects.                           | Some instances, data were collected from a proxy.                             |
|     |                                                                          | Yes (LOW RISK): All data were collected directly from the subjects.           | No (HIGH RISK): In some instances, data were collected from a proxy.          |
| 6.  | Was an acceptable case definition used in the study?                     | An acceptable case definition was used.                                       | An acceptable case definition was NOT used.                                   |
|     |                                                                          | Yes (LOW RISK): An acceptable case definition was used.                       | No (HIGH RISK): An acceptable case definition was NOT used.                   |
| 7.  | Was the study instrument that measured the parameter of interest (e.g. prevalence of low back pain) shown to have reliability and validity (if necessary)? | The study instrument had been shown to have reliability and validity (if this was necessary), e.g. test-retest, piloting, validation in a previous study, etc. | The study instrument had NOT been shown to have reliability or validity (if this was necessary). |
| 8.  | Was the same mode of data collection used for all subjects?              | The same mode of data collection was used for all subjects.                   | The same mode of data collection was NOT used for all subjects.               |
|     |                                                                          | Yes (LOW RISK): The same mode of data collection was used for all subjects.   | No (HIGH RISK): The same mode of data collection was NOT used for all subjects. |
| 9.  | Was the length of the shortest prevalence period for the parameter of interest appropriate? | The shortest prevalence period for the parameter of interest was appropriate (e.g. point prevalence, one-week prevalence, one-year prevalence). | The shortest prevalence period for the parameter of interest was not appropriate (e.g. lifetime prevalence). |
|     |                                                                          | Yes (LOW RISK): The shortest prevalence period for the parameter of interest was appropriate. | No (HIGH RISK): The shortest prevalence period for the parameter of interest was not appropriate (e.g. lifetime prevalence). |
| 10. | Were the numerator(s) and denominator(s) for the parameter of interest appropriate? | The paper presented appropriate numerator(s) AND denominator(s) for the parameter of interest. | The paper did not present numerator(s) AND denominator(s) for the parameter of interest. |
|     |                                                                          | Yes (LOW RISK): The paper presented appropriate numerator(s) AND denominator(s) for the parameter of interest. | No (HIGH RISK): The paper did not present numerator(s) AND denominator(s) for the parameter of interest. |
| 11. | Summary item on the overall risk of study bias                           | There may be errors in the calculation and/or reporting of the numerator and denominator. | There were no errors in the reporting of the numerator(s) AND denominator(s) for the prevalence of low back pain. |
|     |                                                                          | LOW RISK OF BIAS: Further research is very unlikely to change our confidence in the estimate. | The answer is Yes (LOW RISK). |
|     |                                                                          | MODERATE RISK OF BIAS: Further research is likely to have an important impact on our confidence in the estimate and may change the estimate. | The answer is No (HIGH RISK). |
• **HIGH RISK OF BIAS:** Further research is very likely to have an important impact on our confidence in the estimate and is likely to change the estimate.