**Risk of Bias Assessment in Studies of Prescription Errors**

Study ID No. \_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_ Analyst initials \_\_\_\_\_\_

Study:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Unit of analysis is Prescription

Type of error is: Ordering/Prescribing, Transcription, Dispensing

This tool was developed specifically for assessing the risk of bias when estimating overall error rates.

Studies designed to test a new procedure for reducing errors rates, require a different tool.

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| **Topic** | **Evidence** | Rating |
| **1. Selection Bias** | What method was used to identify eligible prescriptions?  a) All prescriptions within a specified time period were included  b) A random sample of eligible prescriptions was taken. Describe random process.  c) A systematic sample of eligible prescriptions was taken. Describe the sampling process.  d) Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Were **all** prescriptions meeting inclusion criteria included in the sample?  Rationale for rating: | Low Unclear High |
| **2. Identification bias** | a) Identify the observation method used.  b) Who was the person who identified the errors?  c) Where/when were the errors identified?  Rationale for rating: | Low Unclear High |
| **3. Error categorization bias** | What system was used to categorize the errors?  a) Recognized system, describe\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  b) Study specific, describe \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Rationale for rating: | Low Unclear High |
| **4. Conflict of Interest** | a) Are study investigators employed by the target institution?  b) Was the study designed to test error prevention strategies (e.g. software) & if so, were any of the investigators involved?  Rationale for rating: | Low Unclear High |

**Directions for Use**

To rate each source of bias, consider the listed factors then decide if the risk for bias is low, unclear, or high. Enter the rationale for your rating in the space provided. Rate the risk as unclear if inadequate information is provided in the article to make a judgment.

**Explanation**

The tool shown here is for descriptive studies for estimating error rates. Hence there are no items related to assessing equivalence of groups, blinding to the intervention, or adherence that are relevant to analytic studies.

1. **Selection bias**: Selection bias refers to how the prescriptions were identified as eligible for the study. The total number of prescriptions identified as eligible for the study becomes the denominator when calculating the error rate. If groups of prescriptions that were eligible were excluded then the total number of prescriptions will be low and the resulting error rate will be higher than it is in reality. In contrast, if a group of prescriptions were included even though they were not eligible, the number of prescriptions would be high and the resulting error rate lower than it is in reality.

2. **Identification bias**: Identification bias refers to the method used to determine if the prescription really does involve an error. Generally speaking some type of consensus process would be used to identify errors, that is, two investigators would review the prescriptions and then meet to resolve in differences in identification based on consensus. The best method is likely a trained observer. Other methods, particularly any method that relies on some type of report is likely to underestimate the number of errors resulting in errors that are lower than they are in reality.

3. **Error categorization bias:** Error categorization bias has to do with how errors were classified. Ideally, a standard, recognized system would be used so that errors can be compared across studies. And ideally, two trained investigators would categorize the errors then resolve differences through consensus. Miscategorization of errors can produce spuriously elevated or decreased errors depending on the category.

4. **Conflict of interest:** Conflict of interest refers to the biases of investigators. Investigators can be biased if they are vested in an intervention (e.g. software) being tested or if the findings may reflect either negatively or positively on their performance.