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| **ASSESSMENT OF RISK OF BIAS (QUALITY CRITERIA)** | | | | | | | | | | | |
| Article number |  | Author |  | Year |  | Date |  | Reviewer |  | | |
| Risk of bias is judged as “low,” “high,” or “unclear.” If the answers to all signaling questions for a domain are “yes,” then risk of bias can be judged low. If any signaling question is answered “no,” potential for bias exists. The “unclear” category should be used only when insufficient data are reported to permit a judgment. | | | | | | | | | | | |
| **Patient selection** | | | | | | | | | | | |
| *Risk of Bias: Could the Selection of Patients Have Introduced Bias? (Two or more No= High)* | | | | | | | | *Low* | | *High* | *Unclear* |
| Signaling question 1: Were subject population of interest specified? | | | | | | | | Yes | | No | Unclear |
| Signaling question 2: Were the sampling method (e.g., at random, consecutive, convenient) for subjects stated? | | | | | | | | Yes | | No | Unclear |
| Signaling question 3: Was *a priori* calculation of the number of patients needed explained according to unique hypothesis (primary end-point) being tested? | | | | | | | | Yes | | No | Unclear |
| Signaling question 4: Was the population demographic data well reported in the Results? | | | | | | | | Yes | | No | Unclear |
| *Applicability: Are There Concerns That the Included Patients and Setting Do Not Match the Review Question?* | | | | | | | | *Low* | | *High* | *Unclear* |
| **Index test (Non-invasive Hemoglobin Monitoring)** | | | | | | | |  | |  |  |
| *Risk of Bias: Could the Conduct or Interpretation of Non-invasive Hemoglobin Monitoring Have Introduced Bias? (Two or more No= High)* | | | | | | | | *Low* | | *High* | *Unclear* |
| Signaling question 1: Were non-invasive hemoglobin measurements of interest described explicitly? (i.e., Name of device, software version, or version of sensor software) | | | | | | | | Yes | | No | Unclear |
| Signaling question 2: Were non-invasive hemoglobin measurements process clearly described to be replicated by other investigator? (i.e., measurement site, protection from ambient light, followed manufacturer instruction etc.) | | | | | | | | Yes | | No | Unclear |
| *Applicability: Are There Concerns That the Noninvasive Hemoglobin Monitoring, Its Conduct, or Its Interpretation Differ From the Review Question?* | | | | | | | | *Low* | | *High* | *Unclear* |
| **Reference standard (Invasive Hemoglobin measurement)** | | | | | | | |  | |  |  |
| *Risk of Bias: Could the Invasive Hemoglobin Measurement, Its Conduct, or Its Interpretation Have Introduced Bias?* | | | | | | | | *Low* | | *High* | *Unclear* |
| Signaling question 1: Was the invasive hemoglobin measurement likely to correctly measure hemoglobin? | | | | | | | | Yes | | No | Unclear |
| Signaling question 2: Were the device name and company of central laboratory device used in invasive hemoglobin measurement clearly described? | | | | | | | | Yes | | No | Unclear |
| *Applicability: Are There Concerns That the Target Condition as Defined by the Invasive Hemoglobin Monitoring Does Not Match the Question?* | | | | | | | | *Low* | | *High* | *Unclear* |
| **Flow and Timing** | | | | | | | |  | |  |  |
| *Risk of Bias: Could the analysis of Flow and Timing Have Introduced Bias?*  *(Unclear: ≥2 unclear, 1 No + 1 unclear) (High: ≥2 No), Not applicable = Yes* | | | | | | | | *Low* | | *High* | *Unclear* |
| Signaling question 1: Was the type of study stated (superiority, equivalent, inferiority)? | | | | | | | | Yes | | No | Unclear |
| Signaling question 2: Were the statistical plan decided *a Priori*? | | | | | | | | Yes | | No | Unclear |
| Signaling question 3: In case of study performing repeated measurements in same patient, did they use statistical analysis for agreement between methods of measurement with multiple observations per individual? | | | | | | | | Yes | | No | Unclear |
| Signaling question 4: Was the interval between non-invasive and invasive hemoglobin measurement appropriate for the study purpose (continuous *vs* point-of-care) and the method of acquiring paired measurements well described? | | | | | | | | Yes | | No | Unclear |
| Signaling question 5: Were number of patients enrolled and who dropped out clearly described in the result? | | | | | | | | Yes | | No | Unclear |
| Signaling question 7: In the case of the bias being described both in text and figures, do they match consistently? | | | | | | | | Yes | | No | Not applicable |

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