

Modified Quality Assessment of Diagnostic Accuracy Studies (QUADAS) Checklist: Validity Studies

Checklist completed by: _____

Study Identification (*Include author, title, year of publication, journal title, pages*) :

Guideline Topic:

Before completing this checklist, consider:

1. Is the paper a validity study? IF NO, consider irrelevant. IF YES continue.
2. Is the paper relevant to key question and has a clear objective?
 Analyse using PICO (Patient or Population, Intervention, Comparison, Outcome).
 IF NO reject. IF YES complete the checklist.

Accepted

Rejected: 1. Paper not relevant to key question 2. Other reason (please specify):

According to Sackett and Haynes, this diagnostic study is considered:

- Phase I
 Phase II
 Phase III
 Phase IV

Phase 1 : Review Question

1. State the review question :

2. Patients (setting, intended use of index test, presentation, prior testing) :

3. Index test(s) :

4. Reference standard and target condition :

Phase 2: Draw a flow diagram for the primary study

Phase 3: Risk of bias and applicability judgments

QUADAS-2 is structured so that 4 key domains are each rated in terms of the risk of bias and the concern regarding applicability to the research question (as defined above). Each key domain has a set of signalling questions to help reach the judgments regarding bias and applicability.

DOMAIN 1: PATIENT SELECTION

A. Risk of Bias

Describe methods of patient selection:

1.1 Was a consecutive or random sample of patients enrolled?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear
Comments:	
1.2 Was a case-control design avoided ?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear
Comments:	
1.3. Did the study avoid inappropriate exclusions?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear
Comments:	
Could the selection of patients have introduced bias?	RISK: <input type="checkbox"/> LOW <input type="checkbox"/> HIGH <input type="checkbox"/> UNCLEAR
Comments:	
B. Concerns regarding applicability	
Describe included patients (prior testing, presentation, intended use of index test and	

setting):	
Is there concern that the included patients do not match the review question?	CONCERN: <input type="checkbox"/> LOW <input type="checkbox"/> HIGH <input type="checkbox"/> UNCLEAR
Comments:	
DOMAIN 2: INDEX TEST(S)	
<i>If more than one index test was used, please complete for each test.</i>	
A. Risk of Bias	
Describe the index test and how it was conducted and interpreted:	
2.1. Were the index test results interpreted without knowledge of the results of the reference standard?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> N/A
Comments:	
2.2. If a threshold was used, was it pre-specified?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> N/A
Comments:	
Could the conduct or interpretation of the index test have introduced bias?	RISK: <input type="checkbox"/> LOW <input type="checkbox"/> HIGH <input type="checkbox"/> UNCLEAR

Comments:	
B. Concerns regarding applicability :	
Is there concern that the index test, its conduct, or interpretation differ from the review question?	CONCERN: <input type="checkbox"/> LOW <input type="checkbox"/> HIGH <input type="checkbox"/> UNCLEAR
Comments:	
DOMAIN 3: REFERENCE STANDARD	
<i>This domain is not applicable for phase 1 studies based on the Sackett classification</i>	
A. Risk of Bias	
3.1. Describe the reference standard and how it was conducted and interpreted:	
Comments:	
3.2. Is the reference standard likely to correctly classify the target condition?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Not applicable
Comments:	
3.3. Were the reference standard results interpreted without knowledge of the results of the index test?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> Not applicable
Comments:	

<p>Could the reference standard, its conduct, or its interpretation have introduced bias?</p>	<p>RISK: <input type="checkbox"/> LOW <input type="checkbox"/> HIGH <input type="checkbox"/> UNCLEAR <input type="checkbox"/> NOT APPLICABLE</p>
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Comments:

B. Concerns regarding applicability

<p>Is there concern that the target condition as defined by the reference standard does not match the review question?</p>	<p>CONCERN: <input type="checkbox"/> LOW <input type="checkbox"/> HIGH <input type="checkbox"/> UNCLEAR <input type="checkbox"/> NOT APPLICABLE</p>
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Comments:

DOMAIN 4: FLOW AND TIMING

A. Risk of Bias

Describe any patients who did not receive the index test(s) and/or reference standard or who were excluded from the 2x2 table (refer to flow diagram):

Describe the time interval and any interventions between index test(s) and reference standard:

<p>4.1. Was there an appropriate interval between index test(s) and reference standard?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> N/A</p>
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Comments:

4.2. Did all patients receive a reference standard?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> N/A
Comments:	
4.3. Did patients receive the same reference standard?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear <input type="checkbox"/> N/A
Comments:	
4.4. Were all patients included in the analysis?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear
Comments:	
Could the patient flow have introduced bias?	RISK: <input type="checkbox"/> LOW <input type="checkbox"/> HIGH <input type="checkbox"/> UNCLEAR
Comments:	
What is your overall assessment of the methodological quality of this study?	Acceptable <input type="checkbox"/> Unacceptable <input type="checkbox"/>

Comments: