

CRITICAL APPRAISAL CHECKLIST FOR AN ARTICLE DESCRIBING A VALIDATION STUDY OF A SCREENING OR DIAGNOSTIC TEST

Note that the questions on the checklist are really looking for problems of bias, confounding, low power, and poor validity.

A. Are the results of the trial valid?	Yes/No/Don't know
1. Did the researchers make the diagnosis independently and blindly with both the test of interest, as well as a 'gold' standard (control) test?	
2. Was the test evaluated in people typical of patients you might expect to see in practice?	
3. Did the study contain enough cases to compare the new test and the gold standard test reliably? * Did the authors include a power calculation?	
4. Were <i>all</i> people diagnosed with both the test of interest as well as the 'gold' standard test (regardless of the results from either)?	
B. What are the results?	
5. Are the test's sensitivity and specificity good enough? * See table below; sensitivity should be high to catch as many cases as possible. Specificity should be high to rule out as many non-cases as possible.	
C. How relevant are the results?	
6. It is possible to get a rough idea of how prevalent the condition you are trying to diagnose is in your patients (pre-test probability)?	

<p>7. Is the diagnostic test likely to be accurate in your patients?</p> <p>* Would its predictive values be good enough for the prevalence of the condition in your patients? (See table below. Positive test results are more likely to be accurate when the condition is more common in people like your patient; negative test results are more likely to be accurate when the condition is less common in people like your patient.)</p>	
<p>8. Will the resulting positive and negative predictive values affect your management and help your patient?</p> <p>* Would the results change management?</p> <p>* Are patients willing to be treated?</p>	
<p>9. Is the test likely to be affordable, available, and acceptable in your setting?</p>	