Diagnostic accuracy study – Basic critical appraisal

1. Did clinicians face diagnostic uncertainty?
Were subjects drawn from a group in which it was not known whether the condition of interest was present or absent? ‘Patients and Methods’ section should tell you this.

This paper: Yes ☐ No ☐ Unclear ☐
Comments:

2. Was the test evaluated in a representative spectrum of patients, similar to those that would be encountered in practice?
Were the full spectrum of cases included – mild to severe, early to late? Random or consecutive selection will minimise bias.

This paper: Yes ☐ No ☐ Unclear ☐
Comments:

3. Was the gold standard test done regardless of the index test results?
The Methods section will tell you this. Ideally, all study participants should have both the test under study, and the reference test.

This paper: Yes ☐ No ☐ Unclear ☐
Comments:

4. Was there an independent, blind comparison between the index test and the ‘gold standard’?
This should be described in the Methods section. The reference standard should be the current ‘best test’ that is closest to ‘truth’. This may include a combination of tests where that is the current way of determining the diagnosis. If you are unsure whether the reference test was the current ‘gold standard’ you may need to look this up. The investigator interpreting the results of each of the tests should be unaware of the results of the other test – i.e. Blinded.

This paper: Yes ☐ No ☐ Unclear ☐
Comments:

5. Were the methods for performing the test described in enough detail for the tests to be replicated??
This should be in the Methods section.

This paper: Yes ☐ No ☐ Unclear ☐
Comments:

What were the results?

6. What is the accuracy of the test?
The sensitivity and specificity reflect the accuracy of the test.

**Sensitivity** is the proportion of people with the condition who have a positive test result. This tells us how well the test identified people with the condition. A highly sensitive test will not miss many people with the condition.

**Specificity** is the proportion of people without the condition who have a negative test result. This tells us how well the test identifies people without the condition. A highly specific test will not falsely identify many people as having the condition.

<table>
<thead>
<tr>
<th>Reference standard</th>
<th>Index test</th>
<th>+ve</th>
<th>-ve</th>
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<tbody>
<tr>
<td>+ve</td>
<td>a</td>
<td>b</td>
<td></td>
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<tr>
<td>-ve</td>
<td>c</td>
<td>d</td>
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Sensitivity = a/a + c
Specificity = d/d + b
### 7. How does the test perform in the population being tested (post-test probabilities)?

**Positive Predictive Value** is the proportion of people with a positive test who have the condition. This tells us how well the test performs in this population. It is dependent on the accuracy of the test (particularly specificity) as well as the prevalence of the condition. In a rare condition, even a test with good specificity may have a low positive predictive value unless the population is enriched for those likely to have the condition.

**Negative Predictive Value** is the proportion of people with a negative test who do not have the condition. This is also dependent on the accuracy of the test and the prevalence of the condition.

From the table above:

- **PPV** = \( \frac{a}{a + b} \)
- **NPV** = \( \frac{d}{d + c} \)

#### PPV of index test:

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#### NPV of index test:

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### 8. Are the results applicable to your patient or a patient in your practice?

Does the test perform differently for different severities of disease? Does the test perform differently for populations with different mixes of competing conditions?

- This paper: **Yes**  □  **No**  □  **Unclear**  □

### 9. Are the results discussed in relation to existing knowledge, and is the discussion biased?

The discussion should place results into a clinical context and the authors conclusions should be justified by the study results.

- This paper: **Yes**  □  **No**  □  **Unclear**  □

### 10. What level of evidence does this paper give?

Can you assign a Level of Evidence using the Oxford CEBM Levels of Evidence hierarch?

- Level of Evidence:
- Comments:

### 11. How would I clearly express the results to a colleague or my patient?

What am I looking for?

- Can you extract data that helps you describe the study findings to a patient or colleague in plain English? Can you perform EBM calculations to help you do this? Can you put the PPV or NPV into a sentence for your patient?

- This paper: **Yes**  □  **No**  □  **Unclear**  □

- **EBM calculation:**
- **Sentence:**