

12 Questions to Help You Make Sense of a Diagnostic Test Study

How to Use This Appraisal Tool

- Three broad issues need to be considered when appraising a diagnostic test:
 - Are the results of the study valid?
 - What are the results?
 - Will the results help me and my patients/population?
- The 12 questions on the following pages are designed to help you think through these issues systematically.
- The first two questions are screening questions and can be answered quickly. If the answer to both is “yes”, it is worth proceeding with the remaining questions.
- You are asked to record a “yes”, “no” or “can’t tell” to most of the questions.
- A number of italicised prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

A. Are the results of the study valid?

Screening Questions

1. Was there a clear question for the study to address?

Yes Can't Tell No

HINT: A question should include information about:

- the population
- the test
- the setting
- the outcomes

2. Was there a comparison with an appropriate reference standard?

Yes Can't Tell No

HINT:

Is this reference test(s) the best available indicator in the circumstances?

Is it worth continuing?

Detailed Questions

3. Did all patients get the diagnostic test and the reference standard?

Yes Can't Tell No

HINT: Consider:

- Were both received regardless of the results of the test of interest?
- Check the 2 x 2 table (Verification bias)

4. Could the results of the test of interest have been influenced by the results of the reference standard?

Yes Can't Tell No

HINT: Consider:

- Was there blinding?
- Were the tests performed independently? (Review bias)

5. Is the disease status of the tested population clearly described?

Yes Can't Tell No

HINT: Consider:

- Presenting symptoms
- Disease stage or severity
- Co-morbidity
- Differential diagnoses (Spectrum bias)

6. Were the methods for performing the test described in sufficient detail?

Yes Can't Tell No

HINT:

Was a protocol followed?

Is it worth continuing?

B. If so, what are the results?

7. What are the results?

HINT: Consider:

- o Are the sensitivity and specificity and/or likelihood ratios presented?
- o Are the results presented in such a way that we can work them out?

8. How sure are we about these results?

HINT: Consider:

- o Could they have occurred by chance?
- o Are there confidence limits?
- o What are they?

C. Will the results help me and my patients/population?

(Consider whether you are primarily interested in the impact on a population or individual level)

9. Can the results be applied to your patients/the population of interest?

- Yes Can't Tell No

HINT:

Do you think your patients / population are so different from those in the study that the results cannot be applied? Such as age, sex, ethnicity and spectrum bias.

10. Can the test be applied to your patient or population of interest?

- Yes Can't Tell No

HINT: Consider:

- o Think of resources and opportunity costs
- o Level and availability of expertise required to interpret the tests
- o Current practice and availability of services

11. Were all outcomes important to the individual or population considered?

- Yes Can't Tell No

HINT: Consider:

- o Will the knowledge of the test result improve patient wellbeing
- o Will the knowledge of the test result lead to a change in patient management?

12. What would be the impact of using this test on your patients/population?
