

CRITICAL APPRAISAL SKILLS PROGRAMME

making sense of evidence

12 questions to help you make sense of a diagnostic test study

General comments

- Three broad issues need to be considered when appraising a diagnostic test:

A/ Are the results of the study valid?

B/ What are the results?

C/ 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.
- The 12 questions are adapted from: Jaesche R, Guyatt GH, Sackett DL, Users' Guides to the Medical Literature, VI. How to use an article about a diagnostic test. JAMA 1994; 271 (5): 389-391.

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A/ Are the results of the study valid?

Screening Questions

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

HINT: A question should include information about:

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

- Yes**
- Can't tell**
- No**
-

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

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

- Yes**
- Can't tell**
- No**
-

Is it worth continuing?

Detailed questions

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

HINT:

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

- Yes**
- Can't tell**
- No**
-

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

HINT: Was there blinding?

Were the tests performed independently?
(Review bias)

- Yes**
- Can't tell**
- No**
-

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

HINT

- Presenting symptoms
 - disease stage or severity
 - co-morbidity
 - differential diagnoses
- (Spectrum bias)

- Yes**
- Can't tell**
- No**
-

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

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

8. How sure are we about these results?

HINT: Consider

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

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.

- Yes
 Can't tell
 No
-

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

HINTS:

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

- Yes
 Can't tell
 No
-

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

HINT:

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

- Yes
 Can't tell
 No

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