

CRITICAL APPRAISAL SKILLS PROGRAMME

Making sense of evidence about clinical effectiveness



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

General comments

- Three broad issues need to be considered when appraising an diagnostic test.

A/ Are the results of the study valid?

B/ What are the results?

C/ Will the results help me and my patient/population?

The 12 questions on the following pages are designed to help you think about 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, V1. 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

<p>1 Was there a clear question for the study to address?</p> <p><i>HINT: A question should include information about?</i></p> <ul style="list-style-type: none"> • The population • The test • The setting • The outcomes 	<p>Yes</p> <input type="checkbox"/>	<p>Can't tell</p> <input type="checkbox"/>	<p>No</p> <input type="checkbox"/>
<p>2 Was there a comparison with an appropriate reference standard?</p> <p><i>HINT: Is this reference test(s) the best available indicator in the circumstances?</i></p>	<p>Yes</p> <input type="checkbox"/>	<p>Can't tell</p> <input type="checkbox"/>	<p>No</p> <input type="checkbox"/>

Is it worth continuing

Detailed Questions

<p>3 Did all patients get the diagnostic test and the reference standard?</p> <p><i>HINT: .</i></p> <ul style="list-style-type: none"> • Were both received regardless of the results of the test of interest • Check the 2 X 2 table <p><i>(verification bias)</i></p>	<p>Yes</p> <input type="checkbox"/>	<p>Can't tell</p> <input type="checkbox"/>	<p>No</p> <input type="checkbox"/>
<p>4 Could the results of the test of interest have been influenced by the results of the reference standard?</p> <p>HINT:</p> <ul style="list-style-type: none"> • Was there blinding? • Were the tests performed independently • (Review Bias) 	<p>Yes</p> <input type="checkbox"/>	<p>Can't tell</p> <input type="checkbox"/>	<p>No</p> <input type="checkbox"/>

<p>5. Is the disease status of the tested population clearly described?</p> <p><i>HINTS:</i></p> <ul style="list-style-type: none"> • <i>Presenting symptoms</i> • <i>Disease stage or severity</i> • <i>Co-morbidity</i> • <i>Differential diagnoses</i> <p><i>(Spectrum Bias).</i></p>	<p>Yes Can't tell No</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>
<p>6 Were the methods for performing the test described in sufficient detail?</p> <p><i>HINTS:</i></p> <ul style="list-style-type: none"> • <i>Was a protocol followed</i> 	<p>Yes Can't tell No</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>

B/ If so, what are the results?

<p>7. What are the results?</p> <p><i>HINTS: consider</i></p> <ul style="list-style-type: none"> • <i>Are the sensitivity and specificity and/or likelihood ratios presented?</i> • <i>Are the results presented in such a way that we can work them out?</i> 	
<p>8 How sure are we about these results?</p> <p><i>HINTS: consider</i></p> <ul style="list-style-type: none"> • <i>Could they have occurred by chance?</i> • <i>Are there confidence limits</i> • <i>What are they?</i> 	

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)

<p>9. Can the results be applied to your patients/the population of interest?</p> <p><i>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.</i></p>	<p>Yes Can't tell No</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>
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<p>10. Can the test be applied to your patient or population of interest?</p> <p><i>HINT:</i></p> <ul style="list-style-type: none"> • <i>Think of resources and opportunity costs</i> • <i>Level and availability of expertise required to interpret the tests</i> • <i>Current practice and availability of services</i> 	<p>Yes <input type="checkbox"/> Can't tell <input type="checkbox"/> No <input type="checkbox"/></p>
<p>11. Were all outcomes important to the individual or population considered?</p> <p><i>HINT:</i></p> <ul style="list-style-type: none"> • <i>Will the knowledge of the test result improve patient wellbeing?</i> • <i>Will the knowledge of the test result lead to a change in patient management?</i> 	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
<p>12. What would be the impact of using this test on your patients/population?</p>	