11 questions to help you evaluate a clinical prediction rule

How to use this appraisal tool

Three broad issues need to be considered when appraising any study:

- Are the results of the study valid?  (Section A)
- What are the results?  (Section B)
- Will the results help locally?  (Section C)

The 11 questions on the following pages are designed to help you think about these issues systematically.

The first three questions are screening questions and can be answered quickly. Only if you can answer “yes” to all three is it likely to be worthwhile continuing with the rest of the questions.

There is some degree of overlap between the questions, you are asked to record a “yes”, “no” or “can’t tell” to most of the questions. A number of 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.

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(A) Are the results of the study valid?

Screening Questions

1. Is the CPR clearly defined?

☐ Yes  ☐ Can’t tell  ☐ No

HINT:
• The type of patients to whom the CPR will be applied is clearly defined?
• The variables included in the rule are clearly defined?
• Is the outcome relevant and is it clinically reasonable? (The outcome can be expressed as a probability or as course of action)

2. The population from which the rule was derived included an appropriate spectrum of patients?

☐ Yes  ☐ Can’t tell  ☐ No

HINT: Consider
• Is it adequate the way the patients were selected?
• The spectrum of patients to whom the rule will apply is well represented?
3. Was the rule validated in a different group of patients?

☐ Yes  ☐ Can’t tell  ☐ No

HINT:
- It is not good enough that the rule had a good performance on the patient group used to derive it. The rule should be validated in a set of patients different from those who served to derive the rule.
- The validation was done in a group of patients similar to the one used to derive it.

Is it worth continuing?

Detailed questions

4. Were the predictor variables and the outcome evaluated in a blinded fashion?

☐ Yes  ☐ Can’t tell  ☐ No

HINT: Did
- People evaluating the outcome know the predictor variables?
- People evaluating the predictor variables know the outcome.
5. Were the predictor variables and the outcome evaluates in the whole sample selected initially?

HINT:
- Are exclusions and drop outs well described and do the authors discuss the reasons for them?
- Sometimes the outcome cannot be measured in the same way in all patients

6. Are the statistical methods used to construct and validate the rule clearly described?

HINT:
- Were all important variables included and the positivity criteria explained?
- The statistical method is adequately described?
- Was the reliability of the rule considered?
### (B) What are the results?

#### 7. Can the performance of the rule be calculated?

**Rule +**

<table>
<thead>
<tr>
<th></th>
<th>Outcome +</th>
<th>Outcome -</th>
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<tbody>
<tr>
<td>Rule +</td>
<td>a</td>
<td>b</td>
</tr>
<tr>
<td>Rule -</td>
<td>c</td>
<td>d</td>
</tr>
</tbody>
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**HINT:**
- Performance results can be presented as: Sens, Sp, + LR, -LR, ROC curve, calibration curves etc.
- Sensitivity = a/(a+c)
- Specificity = d/(b+d)
- LR+ = sens/(1-sp)
- LR- = (1-sens)/sp

#### 8. How precise was the estimate of the treatment effect?

*Did they try to refine the rule with other variables to see whether the precision could be improved or the rule simplified?*

**HINT:** Think about
- The sample size and the number of variables included in the CPR
- Is the rule robust? Has there been any attempt to refine it?
(C) Will the results help locally? / Are the findings applicable to the scenario?

9. Would the prediction rule be reliable and and the results interpretable if used for your patient?  
   - Yes  
   - Can’t tell  
   - No

HINT: Consider

• Is your setting too different from that of the study?

10. Is the rule acceptable in your case?  
    - Yes  
    - Can’t tell  
    - No

HINT: Consider

• The ease of use and the availability of the rule and the costs
• If the rule is reasonable from a clinical point of view
11. Would the results of the rule modify your decision about the management of the patient or the information you can give to him/her?

HINT: Consider

- In addition to your opinion, might there be studies analysing the impact (in monetary terms or health results) of the rule?
- If nothing will change, the rule is at best useless in terms of benefit to the patients.
- How the initial estimation has changed after applying the rule, and the effect it has had on the action threshold.