Reviewer’s report

Title: Development of a clinical decision support tool for diagnostic imaging use in patients with low back pain: a study protocol

Version: 0 Date: 25 Sep 2018

Reviewer: Johannes Reitsma

Reviewer's report:

1. Background: importance of definition of "pathological cause"

Critical for the interpretation of the future results of this study is the exact definition of "pathological cause", in other words what has been considered the target condition. Please provide a better conceptual description in the Background and a more detailed list of causes that will or will not be considered a pathological cause in the Methods. In Background section, indicate how pathological is defined. How it is different than an abnormality? When is something considered pathological, is it based only on expected frequency in the normal population or is prognosis incorporated or whether there is an effective treatment? In Methods section, specifying conditions or abnormalities that will not be considered an outcome may also be helpful.

2. Diagnostic imaging as broad term

The broad term diagnostic imaging is used throughout the manuscript. Please make sure to the reader that the decision not to perform imaging is about all possible imaging techniques but also that the tool is not intended to support the decision which imaging technique to use in case a high risk for a pathological cause.

3. Background: consequences of missed target conditions

The usefulness of support tools for whether or not to perform further testing will be based on the frequency and all consequences related to further testing (well discussed) but also the consequences in case of no further testing. The potential consequences of not identifying pathological causes is not well discussed. Please elaborate.

4. Background: identifying red flags versus multivariable risk prediction tools
After reading the background, it was still unclear to me whether the aim was to identify red flags (presence of individual or combination of characteristics triggering the decision for further testing) or building a multivariable prediction model leading to a predicted probability (based on multiple factors) which will then be used in decision making. From the remainder of the protocol, a multivariable prediction model seems to be the aim. In that case it is good to mention the potential benefit of multivariable prediction model compared to individual red flags.

5. Background: indication of relevant thresholds

In case of multivariable prediction model, a decision has to be made about the use of thresholds. Of course, multivariable prediction models providing an absolute risk probability enable shared decision making, it is still helpful to have an indication what thresholds are likely to be relevant.

6. Methods: established steps (page 7 line 121)

These established steps are not familiar to me. Please elaborate/explain how model performance is different from internal validation. Also explain overall performance. In addition, is external validation and perhaps impact studies also not part of this process?

7. Methods: target population

I was surprised to see that patients with back pain following trauma were part of the target population for two reasons. First, isn't likely that the diagnostic value of certain red flags will differ greatly between these two populations (as there will be different target conditions in these populations? Second, the role of imaging in trauma patents is more complex (broader) and may be used to detect other abnormalities than the spine. Please explain the rationale for including these patients. The background also provides no information on this type of patients.

8. Methods: description of target condition

Information about what is the target condition is given at several places, I like to see a separate section in which all the conditions are listed (including when considered to be present if diagnosis is difficult) that will be considered as target condition being present.

9. Methods & Discussion: procedures to detect target condition
The authors will use a mix of data sources to collect information whether the target condition was initially present. However, there is no standardization with testing needs to be done. In the Discussion the consequences of this approach need to be discussed in light of the potential alternative: to perform imaging in all patients.

10. Methods: model development

Continuous factors will be examined in their original form. However, on page 12 line 228 there is still the mentioning of dichotomization or categorization. In a multivariable prediction model this is not necessary: thresholds for defining further actions can be based on the predicted probability (so at the end).

11. Methods: interaction

Specifically indicate whether or not interactions will be examined.

12. Methods: missing values

The study uses data from different sources including administrative and routine care data which are likely to have missing values. Please explain how missing values will be handled.

13. Methods: non-linear recursive partitioning strategy

The role of this additional modelling strategy is not clear. Do the authors consider the logistic model and partitioning strategy as competing models, and if so how will they determine which one is best? Or will these different strategies inform each other and will they be combined into a supermodel. Please explain the role of the additional modelling strategy.

14. Methods: sample size considerations

The 1:10 rule is currently under debate and can be considered as a kind of minimum to avoid fitting problems. Once a more explicit role of the prediction model has been formulated, the authors may provide insight how accurate predictions are likely to be at specific meaningful range of probabilities. For instance, if a predicted probability of 5% or lower will be used as a threshold to refrain from further testing, it is useful to estimate how many patients will be given such a score. It provides insight how precise the associated error rates can be estimated.
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