Reviewer’s report

Title: Development and validation of a clinical prediction model to risk stratify patients presenting with small pulmonary nodules. A research protocol

Version: 0 Date: 02 Oct 2018

Reviewer: Vanesa Bellou

Reviewer's report:

The authors aim to develop a prediction model to stratify patients presenting with lung nodules in clinical practice according to risk of malignancy. I believe this is an important topic to address, given the clinical significance and the high prevalence of lung nodules. I have a few modifications to suggest.

1) The introduction section recites Fleishner and BTS guidelines for monitoring of lung nodules according to the size. I understand the rationale for including this in the manuscript but it occupies a large part of the introduction and can be hard to follow for non-specialists. I would propose to include this information in a table, which is easier to comprehend.

2) It would be helpful to deemphasize on the size of the lung nodule, as stated in the previous comment, and mention other factors they use in their prediction model, eg other radiographic characteristics of lung nodules (size, density, etc) as well as patient characteristics (age, history, etc) and their significance as predictors of malignancy in the introduction section.

3) The authors mention a number of other prediction models previously developed for the same outcome. They mention only validation study of one of the prediction tools in the UK. It would be useful to add countries/continents, clinical setting and ethnicity of participants used for each model in the development and the validation study.

4) Given that this study is based in UK patients, it is important to mention the procedure for a referral for a CT in the national health system. This is to helpful to appraise the external validity of findings, considering that regulation of referrals for computed tomography is dependent of the structure of the national health system.

5) Please elaborate on your rationale for including the specific variables for your prediction model as well as you will each variable (eg categorical, continuous)

6) For the assessment of the outcome please elaborate on how will nodule will be assessed (follow up period and size comparison)
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**Quality of written English**  
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Acceptable

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