Reviewer’s report

Title: Use of Test Accuracy Study Design Labels in NICE’s Diagnostic Guidance

Version: 0 Date: 25 Feb 2019

Reviewer: Susan Mallett

Reviewer's report:

This is an important paper, drawing attention to the muddled terminology in diagnostic studies. I have very few suggestions as I think it is a good paper as it is.

I would like it to go that bold step forward and suggest that the DTA research community could use table 2 as a framework for studies to identify and report on key features of study design.

I particularly like table 2 and offer the following suggestions. I think this table could be worked up into a framework for what should be clarified in describing a study, as it is your derivation of concepts that need to be described. So it would become the start of a way forward, more as part of a reporting guideline with recommended terminology? Maybe you will think this one step too far for this article, in which case I would still change its concept to define what needs to be described. At the moment I think it describes the muddle, rather than being a valuable contribution to the start of straightening it out?

* Table 2 title - Should it be something like key design features.

* Number of index test - ? change to different feature heading as this is not the same as comparative concept (direct or indirect) as a study could report on a number of tests, but not aim to compare them.

* Who receives the different tests - are you including the concept of randomisation to reference test - or only to different index tests? What does comparator refer to here - seems to overlap to "head to head" index tests.

* Order of tests - needs a few more words are needed to describe

* Adding a few words in Table 2 Eligibility heading. Suggestion "Eligibility: number of included groups"

* Eligibility - inclusion criteria - do you mean "Asymptomatic, symptomatic, high risk groups"
* Can we move away from the wording "consecutive" as in my experience there is no such study. I have used the following wording in a recent paper "recruited consecutive (i.e. unselected) eligible patients." Meaning they were as consecutive as possible, whilst not 100% consecutive as I do not believe this is ever possible. I don't really like my wording, as they were selected by the inclusion criteria - so maybe there is something better?

* Recruitment setting - maybe split up single centre and location - this is two important concepts in one heading.

* Data collection "conduct/time of the index and reference standard" - this one is tricky. In many cases it is about when the sample was taken for a biomarker, rather than when the sample was unfrozen and the test done. Maybe this just needs a footnote, that where stored samples are used, this is relative to the date of sample collection.

* Analysis - can you make this clearer? What are you meaning by discordant case analysis (you pointed out the two definitions in table 1)? Post-hoc analysis of prospective data - sometimes this is OK if the data were collected with a protocol and is fit for purpose.

* I really like the concept from Ida Sim about protocol driven data collectoin or non-protocol driven data (databases). Can this be included somewhere maybe at the top, as this is so critical to many of the biases.

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