Reviewer’s report

Title: Validity Testing of a Measure of Prostate Cancer Screening Anxiety

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Reviewer: Wolfgang Linden

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This manuscript describes validation efforts for a measure of anxiety associated with prostate cancer screening. The researchers have assembled a brief 3-factor questionnaire that tries to tap into anxiety around the overall process of prostate cancer screening as well as specific fears around rectal examination and PSA test. Two samples are being used for the validation effort in the hope that the same results could be obtained in both samples. One sample is roughly n=150 and the other twice the size; one is from a private clinic, the other from the public clinic.

The work described here has some distinct strengths in that the researchers set out a very reasonable and promising validation strategy and use very sophisticated statistics to derive at their conclusions. This aspect is strong and convincing.

Unfortunately this sophisticated analysis is executed on a data set that is problematic and the development of the tool has some questionable premises. Here are specific points:

[1] the typical target individual for prostate cancer screening is a male who is 50 to 80 years old. Older men have exceptionally low anxiety levels and this continues to be true even in men who have a positive diagnosis of prostate cancer. I’ve seen this in multiple publications and in our own data. This fact suggests that any work related to anxiety in these men is likely going to suffer from a floor effect such that anxiety reduction is not likely and that the range of anxiety scores will also likely be limited. As it turns out, this applied indeed to the samples described here and this fact is acknowledged by the authors themselves in the discussion.

[2] from my vantage point, the order of some of the steps in the tool development is backwards. The authors argue that emotional responses to physical illnesses are best assessed with disease specific tools and I agree. Nevertheless they began their item development by using Spielberger’s anxiety scale items as the basis and then later had a very small sample of prostate cancer patients comment on the items that the team had developed. When it comes to content validity I think it would have been much better to capture the content domain by talking to patients first, via focus groups or similar qualitative approaches and develop items afterwards. This weakness of order of steps becomes apparent in the fact that of the three factors that presumably existed in the item pool, only one reflects good psychometrics and is recommended for use by the authors. Not surprisingly, it is the overall screening anxiety subscale that survives and we
still don’t know what exactly, if anything, these men are scared of. I remain unclear what the resulting scale can be used for.

It appears to me that at this stage the best advice researchers can give clinicians is to ask patients how much knowledge they have and how much knowledge they want before making a decision, and then to give them as much information as they request.

[3] A really big problem is revealed in the numerous important differences and results between the 2 samples. Given that one is private and the other one is public, it is not surprising that the clinic patients differ in terms of race and ethnicity, in SES, and especially in knowledge. The authors acknowledge this. For validation of this questionnaire it makes sense to start with two samples that are equivalent in knowledge (and maybe a few other variable like race and age). These differences in the samples and corresponding non-replicability of some analyses means that at least to some degree the results are un-interpretable.

[4] there are a few typos and oddly written phrases in the manuscript; it should be proofread by an outsider for clarity and correctness.

The bottom line for me is that the tool is not ready for use and the tool development and validation process not sufficiently advanced to warrant publication. Note that we don’t know anything about test retest reliability. Unfortunately I do not see much added theoretical or practical importance

**Level of interest:** An article of limited interest

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No, the manuscript does not need to be seen by a statistician.