Author's response to reviews

Title: Patient safety culture measurement in general practice. Clinimetric properties of SCOPE

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Version: 2 Date: 31 August 2011

Author's response to reviews: see over
Revision of manuscript ‘Patient safety culture measurement in primary care. Clinimetric properties of ‘SCOPE’.

August 30th

Dear editor,

Hereby we send you the revision of our manuscript and our reactions and answers to the reviewers’ comments. We would like to thank the reviewers for their helpful comments and questions.

Below we have copied the comments and addressed them point by point. Also, we added the phrases we changed in the manuscript to this letter. In the revised manuscript these changes are marked red.

We hope that the current revision will be satisfactory and we would like to thank you in advance for your time reviewing this revision of our manuscript.

On behalf of all authors,

Yours sincerely,

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Reviewer's report

Title: Patient safety culture measurement in primary care. Clinimetric properties of SCOPE

Version: 1 Date: 11 April 2011

Reviewer: Panayota Sourtzi

Reviewer’s report:

The research reported in this article is of interest to everyone working in primary health care.

First, we would like to thank the reviewer for the helpful comments.

The following minor revisions could improve the article.

1. A paragraph explaining the primary health care team responsibilities in the Dutch health care system could help international readership understand why you used a mixed sample in the examination of the metric properties of the instrument.

In order to explain why we examined the psychometric properties on a mixed sample we added the following paragraph to the methods section:

In the Dutch primary care setting GPs, medical assistants and practice nurses work closely together in small practice teams. Besides diagnosing and estimating the urgency of new health problems, GP practices offer preventive services, geriatric and paediatric support, management of chronic diseases and minor surgery. The GPs provide the medical care and usually are responsible for practice management. The medical assistants and practice nurses execute both administrative or organisational tasks and preventive medical care. In some practices physiotherapists and managers are part of the practice teams as well. Because SCOPE aimed at assessing safety culture in general practice, the practice teams were chosen as study population. Hence, in each practice all staff, including GPs, MNs, practice managers and physiotherapists was asked to participate.

2. The study sample consists of physicians and nurses. However, neither in the text nor in the tables there is separate reference in these two subsamples. In my opinion it would be interesting to see if
there are differences in the clinimetric properties between the subsamples and this could add to the validity of the instrument.

We agree that it is interesting to study the clinimetric properties of the subsamples; however, while the subsample of GPs was rather small (n= 73) and to maintain the focus on construct validity we have not presented these figures.

2. In table 1 there is detailed reference in the demographic data of GPs. In my opinion detailed data of the nursing sample should also be presented although as it is noted there are no reference data.

We have added available demographic data in table 1 about the medical assistants and practice nurses as requested by the reviewer.

3. language improvements
in page 3, 1st paragraph,4th line: reverse words "not has" to "has not"
in the same page, last paragraph, 1st line: add the word "setting" after primary care

We have changed the wording according to the reviewers’ (1 and 2) suggestions.

Reviewer’s report 2
Title: Patient safety culture measurement in primary care. Clinimetric properties of SCOPE
Version: 1 Date: 15 April 2011
Reviewer: Barbara Hoffmann

Reviewer’s report:
Thank you for this paper and the opportunity to comment on it. It reports on an important subject that had not been of much attention in the past: patient safety culture in general practice. It demonstrates the results of an important project that adds valuably to the scientific knowledge. It deserves publication with only minor, but essential revisions.
We thank the reviewer for her thorough and helpful comments.

General comments:

1. Context: In the manuscript (and the title) the terms primary care and general practice are used interchangeably. However, the questionnaire deals with safety culture in general practices. Is primary care in the Netherlands just general practice? If the answer is no terms should be made clear.

Primary care and general practice are not exactly the same but are commonly used interchangeably in The Netherlands. For clarity of the manuscript we will follow the reviewer’s suggestion and change ‘primary care’ in ‘general practice’ in the manuscript, wherever appropriate.

2. There is some debate on whether it is safety climate or safety culture that is being measured by questionnaires (e.g. Halligan et al. BMJ QualSaf 2011; Guldenmund Risk Analysis 2011). I would advise to refer to the debate and clarify what exactly the term should be in the context of this study.

To address this issue, we added a paragraph to the introduction and added the suggested references:

There is an ongoing debate on the validity of quantitatively measuring culture; surveys may only assess ‘climate’ which refers to individual opinions and attitudes, rather than ‘culture’ which concerns underlying shared values and assumptions (refs). We acknowledge the value of this distinction between ‘climate’ and ‘culture’. However, as both terms are used interchangeably in different publications and this discussion does not immediately affect our results, we only applied the term ‘culture’ in this paper.

Introduction:

3. Safety culture is widely accepted to have an impact on patient safety though the evidence is still quite small. Please refer to more current literature that actually show an empirical link between the both (e.g. Mardon et al. J Pat Safety 2010; Haynes et al. BMJ QualSaf 2011). Please be more precise in the abstract: “A supportive patient safety culture is supposed to be an important.....”
We thank the reviewer for the literature suggestions. We have added these with the following sentence in the introduction section:

**Recent publications suggest a similar relationship in healthcare (refs).**

In addition, we followed the suggestion of the reviewer specifying the abstract by adding:

**A supportive patient safety culture is considered to be an essential condition for improving patient safety**

4. The Medical Office Survey on Patient Safety Culture of the AHRQ is available since 2007 or 2008. Please add the information (my guess) that you were already developing SCOPE from the Dutch HSOPS when the other questionnaire had been made public. I recommend a discussion of both contents and factor structure later in the article.

As the reviewer had guessed, we already started revising the Dutch HSOPS early 2006. At that time the Medical Office Survey on Patient Safety Culture of the AHRQ was not available yet.

In the manuscript we added:

‘As at the time of the start of this study (2006) all available surveys originated from hospital care (26-28)…’

**Methods:**

1. Did you undertake cognitive testing? Did the pre-test panel meet personally? Was adaptation a team process with face-to-face meetings? Please add the information in the manuscript.

We did not undertake formal cognitive testing in the pre test phase. The pre-test panel did not meet personally; each member provided written comments on the first draft of the SCOPE and, if anything was unclear, was contacted by one of the authors (RvdV) to discuss the comments and suggestions personally.
The panel did not meet in person, but communicated by e-mail, or individually with a researcher (RvdV).

2. Data collection and participants: As I understand the way of data collection the questionnaire had been “administered” online (Did participants have to log on to the web site, did they need a personal login or a practice login? Please provide this information in the manuscript). Do you know how many of eligible individual participants (in the 72 participating practices) actually took part in the study?

All participants had a practice login-code, but were subsequently provided a personal questionnaire.

We do not know the exact number of eligible participants in the 72 practices, but we do know that the median number of practice size is 6 persons, and the mean is 6.9. Thus, the estimate number of participants is between 432 and 497 caretakers.

3. Data collection: Why was data collection stopped after five months (Had been a required number of participants achieved?)? Please add the required information.

The most important condition for stopping data collection was a least number of respondents > 300. Furthermore, 5 months was the pre agreed data collection period in order to meet the targets set in our grant.

We added in the description of the data collection: After a pre agreed period of five months……etc.

4. Factor analysis: “Items that loaded on more than one factor were excluded”. Due to my experience I would expect that at least some of the items load on more than on one factor with loadings of more than 0.4 (all the more there are few considerable inter-factor correlations). Please comment on this remark.

We did not find items that loaded with more than .4 on more than one factor.

5. Internal consistency: I would like to indicate that there are different perceptions of Cronbach’s alpha that consider a value of 0.7 as acceptable (“recommended”) and of 0.8 as good (e.g. Streiner DL. Starting at the beginning: An introduction to coefficient alpha and internal consistency. J Pers Assessment 2003;80:99-103). On the other hand, cronbach’s alpha depends on the number of item
per factor and therefore a three item factor with an alpha of 0.65 seems to be quite good. Please comment on this in the manuscript.

We agree with the reviewer that there are different perceptions of Cronbach’s alpha, and that the value of .7 is recommended. In our study we also found several alpha’s between .64 and .7; we interpreted these values as fair. Several authors interpreted a Cronbach’s alpha between .6 and .7 as fair, and an alpha between .7 and .9 as good. (e.g. de Boer MR, Moll AC, de Vet HC, Terwee CB, Völker-Dieben HJ, van Rens GH. Psychometric properties of vision-related quality of life questionnaires: a systematic review. as our study was a first analysis on the concept of safety culture in general practice.) However, as SCOPE has eight subscales with alpha’s ranging between .64 and .85 we interpreted the overall internal consistency as acceptable following Bland and Altman. (Bland JM, Altman DG. Cronbach’s alpha. BMJ. 1997 Feb 22;314(7080):572.)

6. Please give the information on the way how you interpreted the average inter-item-correlation and evidence on the limit of 0.2 to 0.7 (there are recommendations that it should range between 0.2 and 0.4).

We used inter item correlations as an additional test voor studying construct validity. We started from the assumption that an inter-item correlation between 0.20 and 0.70 was a satisfactory indication of non-redundancy of each scale. To set these limits we followed several authors e.g. Lamping CHEST September 2002 vol. 122 no. 3 920-929 and Bot SD, Terwee CB, van der Windt DA, Feleus A, Bierma-Zeinstra SM, Knol DL, Bouter LM, Dekker J. Internal consistency and validity of a new physical workload questionnaire. Occup Environ Med. 2004 Dec;61(12):980-6.

7. Construct validity: A limit of 0.7 is given to distinguish between high correlations and acceptable correlations. Please provide a reference since according to my experience a correlation of e. g. 0.6 is widely accepted as being quite high.

In this question it was unclear to us whether the reviewer refers to the limit of Cronbach’s alpha we applied or to the limit of the average inter item correlation. If the question regards Cronbach’s alpha we would like to refer to our answer to point 5 in this section. If it concerns the inter item correlation limits we would like to refer to our answer to point 6 above.
Results:

1. Please provide a response rate (either on practice level or individual level).

The estimate response rate is between 67 and 76% (based on an estimate of 432 and 497 eligible participants and a response by 331 caretakers). We added the most conservative response rate in a sentence in the results section:

A total of 331 respondents from 72 practices with estimated 497 eligible participants (response rate 67%) returned the questionnaire between February and July 2009.

2. What was the limit for representativeness? By looking at the data it seems to me that the study population had more work experience than the national average. Had been statistical analysis been done or is this purely descriptive? Please comment on that.

We did not set any limit for representativeness and only described the study population, as data on representativeness are not available for the majority of the study population, namely the medical assistants and practice nurses.

3. How do you interpret the results of average inter-item correlations and item-rest correlations? Please add the interpretation in the manuscript.

We added the interpretation of the correlations to the first sentence of the discussion section of the manuscript.

4. The lower range of Cronbach’s alpha values: Please see my comment to the method section, no 5.

In this matter we would like to refer to our answer on point 5 method section.
5. Did the 72 practices dispose of local reporting systems? A short information on the opportunities of participants to report would add valuable information to this result. Did you evaluate these opportunities as well?

Previously, an evaluation on national level had shown that almost no GP practice had an opportunity to report incidents. To elicit this matter we added a sentence to the method section, under the description of the eligible participants:

**At the time of the survey, most GP practices did not have a reporting procedure; SCOPE was offered as a voluntary first step towards concretizing safety management requirements.**

Discussion:

1. I would like to recommend to revise the summary to “…the internal consistency...were mostly satisfactory”.

We followed the suggestion of the reviewer and added to the first paragraph of the discussion:

In the eight-factor model, the internal consistency of the factors and the construct validity of the SCOPE questionnaire were **mostly** satisfactory

2. In the paragraph on incident reporting the term safety culture is used normatively (how a culture of safety should look like). I would like to recommend to distinguish thoroughly between an analytic approach and the use of terms (that uses questionnaires to measure the various aspects of safety climate) and a pragmatic approach (see Guldenmund Risk Analysis 2011). The way you used the questionnaire safety culture could be “good” or “bad” and we believe that a “good” safety culture disposes of successful incident reporting and learning.

[dt]

In this comment the reviewer recommends to distinguish between an analytical approach and a pragmatic approach to safety culture as described by Guldenmund in Risk Analysis 2010. However, with our decision to sustain the subscale on incident reporting, we did not intend to set a norm (which would be a shift to the pragmatic approach), but we intended to anticipate on a response shift (the clinimetric term) that is likely, considering the developments around patient safety management. To clarify our argument, we changed some sentences in the paragraph on incident reporting in the discussion section:
This may indicate that, as incident reporting in Dutch general practices is still very uncommon, it is currently not perceived as an integral part of a patient safety culture in GP practices. Yet, we decided to maintain the subscale about intention to report because it is likely that some form of incident reporting will increase in general practice as part of patient safety interventions in the near future which may lead to a change in the patient safety culture concept in general practice.

References:

1. Please revise the whole section carefully – there seem to be still some data on references missing (e.g. 25 and 29), some copied data from a reference manager (25 and 32; “Ref Type: generic”). Ref no. 14 is published 1999. And ref no. 9 is already published.

We revised the references following the reviewer’s suggestions.