Author's response to reviews

Title: The association of smoking status with healthcare utilisation, productivity loss and resulting costs: results from the population-based KORA F4 study

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Author's response to reviews: see over
Dear Editors,

Thank you very much for providing us with the opportunity to revise our manuscript MS: 9241983717911021 and re-submit.

We are also grateful to the reviewers for their valuable comments. We are pleased to let you know that all comments by the reviewers and editors have been taken into account in this revision. All modifications made in the revised manuscript are addressed within the point-to-point response. As recommended, we also sought the assistance of an English language editor who checked the manuscript.

Please find attached point-to-point responses to the comments and the revised manuscript.

We are convinced that the reworked manuscript addresses all previous points of concern in a satisfying manner and thus resubmit our paper to “BMC Health Services Research”.

Thanking you and looking forward to hearing from you soon.

With kind regards,

Margarethe Wacker
Reviewer's report:
The papers has been satisfactory reviewed. Most past of the reviewers' comments addressed. Thank you very much!!

I would just add some minor comments that would be very much appreciated if they are addressed before publication:

1. Abstract: In the methods section, there is a sentence "Unit costs were applied to utilisation..." that is too long and very hard to understand. Please, could you rephrase it?

   Thank you for this comment: we improved this sentence as follows:
   "Unit costs from a societal perspective were applied to utilisation. Utilisation and resulting costs from a societal perspective were compared across different smoking groups using generalised linear models to adjust for age, sex, education, alcohol consumption and physical activity."

2. Abstract: In the results section, you said "Average annual total costs per survey participant...". Please, could you specify if this survey participant, if this average annual cost belongs to a smoker, former smoker or never smoker?

   Thank you for this remark: €3,844 are per capita unadjusted mean total annual costs for all survey participants. In order to underline the differences between groups, we added exemplarily unadjusted mean costs for former smokers and never smokers, please see p.3. "Average annual total costs per survey participant were estimated as €3,844 [95% confidence interval: 3,447-4,233], and differed considerably between smoking groups with never smokers showing €3,237 [2,802-3,735] and former smokers causing €4,398 [3,796-5,058]."

3. Background: In the second line "The list of diseases caused...". please, I think you could include a reference for this sentence!

   We agree with you and added an appropriate reference, see [2].

4. Results: In the First paragraph (Unadjusted analyses), the sentence "Overall, mean total annual costs were €3,844..." needs to report whether is per smoker patient, or former smoker, etc...
As described above, €3,844 are per capita unadjusted mean total annual costs for all survey participants. We added this explanation to the manuscript, see p.12. Unadjusted means per smoking groups are reported in the same paragraph and details can be found in Table A2 in the appendix.

5. Results: In the second paragraph (Regression analysis) about the sentence "Current smokers showed significantly lower odds ratios for physician visits..." I think that you should incorporate in the discussion the implications of this lower odds ratios for current smokers, if there are any.

Our findings that current smokers showed a lower probability of physician treatments, but a higher number of treatments if they had used physician treatments at least once could be explained by several speculations:

First of all, there may be a “healthy smoker effect” whereby sick smokers selectively quit smoking at greater rates than healthy smokers. Furthermore, special attitudes of smokers (e.g. smokers may tend to ignore health risks or they do not look after themselves or could be deterred from seeking healthcare through fear of discriminations and feelings of guilt) may translate into denial of illness and to delays in seeking care. Once seeking healthcare is unavoidable, their health problems may be more advanced and may require special treatments.

These findings are in line with other studies on healthcare utilization of smokers, see e.g. [44].

We added one sentence on possible reasons for this pattern, see p.15. “This pattern could be explained by the possibility of a healthy smoker effect or special attitudes of smokers which translate into denial of disease and delays in seeking healthcare [44].”

A more detailed discussion of all differences in the healthcare categories would go beyond the scope of this paper, as utilizations patterns are finally translated into costs which are the focus of this manuscript.

6. Discussion: In the second paragraph, about the sentence "Our findings that current smokers showed a lower..." should specify compared to what current smokers showed a lower probability of physicians treatments.

We agree with you and added “compared to never smokers” as explanation, as never smokers are the reference group for all analyses in this work, see p.15.

7. Discussion: In the thirs paragraph, about the sentence "Nevertheless, subsample analysis showed that even former smokers...", please, could you state or size how much costs in average cost former smokers compared to smokers?

Thank you for this remark. We underlined the findings of the subsample analysis with numbers, please see p.15: “Within the subsample of former smokers, we observed that those who had quit smoking in the previous 12 months caused considerably higher total costs
than those who had quit more than 12 months previously (factor 2.37, p=0.0005). ...
... Nevertheless, subsample analysis showed that even former smokers who had quit more than 10 years ago cause higher total annual costs than current smokers (28% vs. 23% higher total costs compared to never smokers, p=0.002).”

8. and, Discussion: End of page 15, about the sentence "Disregarding issues of representativeness...''...please, could you report why and how sensible could be your results in terms of representativeness?

- In general, due to high recruitment efforts in the KORA studies, high representativeness of our study sample can be expected. Nevertheless, as already discussed on p.18, we cannot exclude the possibility of selection bias as current smokers had a lower follow up rate than other smoking groups. In consequence, our results could be systematically under- or overestimated. This fact, which is mentioned as a limitation on p.18, needs to be kept in mind when interpreting our results.
Reviewer's report:

This study addresses the important issue of the impact of smoking on healthcare costs, direct medical costs and productivity losses for different groups of smokers in Germany. Thank you for addressing the concerns from the first review. The manuscript is considerably improved and the authors were highly responsive to the comments by outlining their responses and rationale. The authors addressed all the issues identified. Just a few areas remain that need clarification so a few last changes would improve the manuscript. I still have the following concerns:

Minor Essential Revisions
1. Please specify the design from the study under ‘Methods: data and study design’. Although in the Abstract and Discussion it is mentioned that the study was cross-sectional, this information is lacking in the relevant section. From the first version of the manuscript it was not absolutely clear that survey and healthcare costs and productivity losses where only measured in the F4 study (and thus the design of the study was only cross-sectional). The authors might therefore also consider mentioning explicitly that only F4 data was used for this study and analysis, and not the S4 data (since costs where not measured in S4).

   Thank you for this remark: we added “cross-sectional” in the methods section, please see p.7.
   “Thus, the final study sample for this cross-sectional F4 analysis contained 3,071 subjects.”

2. Indirect costs (p.8). It is still not mentioned that in Germany the maximum number of working days is 213, and therefore the authors chose this number. Please insert this information since otherwise the number of 213 remains an arbitrary number.

   We improved the explanation for the restriction to 213 days, please see p.9:
   “If participants stated a greater number of days of absence from work than the maximum number of 213 working days in 2008 in Germany, their days of absenteeism were restricted to 213 (n=6).”

Discretionary Revisions
1. The authors have added detailed definition of the classification of smokers, occasional smokers, former-smokers and never smokers to the Methods section. The distinction between former smokers who smoked occasionally and never smokers who may have smoked less than 100 cigarettes in their lifetime seems to be arbitrary and highly subjective to recall bias. This shortcoming may additionally be discussed in the Discussion section.
– We added the possibility of recall bias regarding smoking behavior in the past to the discussion section, see p.18.

2. Some minor language errors (punctuation, grammar) remain. Please reread carefully to avoid errors in the final version of the manuscript.

– Thank you very much for this advice. We re-read the manuscript and we could eliminate errors in spelling, punctuation and formatting.
Reviewer's report:
Minor Essential Revisions
The authors have done a very good job at addressing my concerns. My only remaining concern refers to my original comment about the use of the negative binomial model as the second part of the two-part model. My further response is listed below the authors reply to my original comment.

4. Statistical Analysis: The use of the negative binomial regression for “users only” seems slightly strange given that the negative binomial also supports zero use even though by construction the “users” will only have non-zero usage? Some clarification here would be welcomed about why a zero-truncated model was not used or why the negative binomial is more appropriate in this case?

- You are right in that the negative binomial also supports zero-valued observations. However, there are excess zeros in most of our healthcare categories (e.g. for alternative practitioners, where 2,850 out of 3,068 participants did not report health care use). In such situations, the amount of zeros is usually much higher than expected under the count process assumed for the remaining observations with non-zero use. This is why we preferred to model zero counts and non-zero counts separately.

• I understand the excess zero problem and I have no issues with you using a two part model – my concern involves the use of the negative binomial as the second part of the model. In particular you have gone from the case where you had too many zero to the other extreme where you now have too few zeros (none) for the negative binominal model. A regular negative binomial model will try to predict zero counts even though in your case there are no zeros in the second part of your model. Ideally I would have preferred a zero-truncated negative binomial model as the second part of the model. I would be more comfortable if this issue was noted in the text for others looking at following your methods to consider.

– Thank you very much for this valuable and useful explanation. We recalculated Table 3 of our analysis using a zero-truncated negative binomial model which you proposed, instead of the negative binomial model. Consequently, the concept of a hurdle model is realized by step 1 (logistic regression, see table 2) and step 2 (zero-truncated negative binomial, see table 3). Results hardly changed between the negative binomial model and the zero-truncated negative binomial model. Nevertheless, we agree with you that this approach is correct. Please find the results of the recalculation in Table 3 and the online-appendix Table A4.