Author’s response to reviews

Title: The EMPCAN Study: Study of The Evolution of The Socio-Economic Position of Workers With Cancer. Study Protocol of a Population-Based Cohort Study.

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Author’s response to reviews:

Ok, the Methods section is now clearer in the abstract but not in the manuscript.

My major concern is that the Methods section is still not well written. I mean that this section does not follow the recommendations in terms of protocol publication.

The authors said that they completely reviewed the methods section but nothing has been changed except the added first paragraph. I think that the first paragraph is helpful. We have a lot of data in the Methods section but it is not always comprehensive because of the lack of structure (headings and subheadings are needed).

ANSWER: I understand and agree on your point. I’ve tried to be this time more clear, but I did not really “re-write” the section as I think that you main concern was the structure. I’ve used more headings, added some sections according to your advices and completed others.
For example, I asked to add a separate section on the study population with inclusion and exclusion criteria. The author answer was: "We believe that the lines 205-213 describe this inclusion/exclusion criteria + the figure 4". The lines 205-213 are: "The main points under discussion concerned the definition of the cohort (inclusion and exclusion criteria) and the choice of the variables which were the most appropriate regarding the study objectives, i.e. the discussion of the proportionality principle. For the technical and ethical aspects, we received advices and recommendations of lawyers from the governmental platform eHealth. As there was no precedent of such data coupling in Belgium, these different steps of coupling and controlling privacy, required more than two years to finally submit our demand to the national Privacy Commission, which provided its positive opinion in January 2016". I do not understand how these lines are a presentation of the study population. Perhaps the authors meant more precisely about the lines 223-227: "The BCR started the process, with the selection of patients diagnosed from 1st January 2004 to 31st December 2011 included, with: head and neck cancer (C00-C14 and C30-C32); lung cancer (C34); colorectal cancer (C18-C20); breast cancer (C50); corpus uteri (C54); prostate (C61) and testis cancer (C62). Among them, the BCR only retained those aged 16-64 at the date of incidence". Nevertheless, there are not enough details for a protocol.

ANSWER: I think that I was referring to the lines of the documents with the track changes which doesn’t correspond to the lines of the “clean” version. I am very sorry.

In any case, I have used your suggested headings to restructure the methods section. I’ve highlighted those that I found the most appropriate for this protocol. Many thanks for that.

In addition, I cannot read figure 4 because of the picture quality.

ANSWER: I added a word version of the Figure 4 so that you can may be easier read it. For the editorial team it seemed ok…

Here is an example of the data (corresponding to headings and subheadings) that should be found in a protocol: * Description of the study * Study Population o Approximate Number of Subjects / sample o Inclusion Criteria o Exclusion Criteria * Recruitment * Study Duration o Approximate Duration of Subject Participation o Approximate Duration of Study * Procedures / Data collection / Study Flow Diagram * Data Management o Data Collection and Storage o Records Retention * Data analysis o Statistical Analysis Plan o Statistical Power and Sample Size Considerations * Protection of human subjects o Informed Consent o Data Monitoring Plan o Insurance o Ethical approval * Publication plan
I agree that there are a lot of these data in the actual manuscript but there is a lack of structure that is essential for the presentation of a protocol study.

ANSWER: I’ve used 9 of the headings that you suggested, I hope that it now makes it clearer.

In addition, some parts of the manuscript should be more detailed as for example: * Lines 209-210: For the technical and ethical aspects, we received advices and recommendations of lawyers from the governmental platform eHealth. => Which advices and recommendations? It should be presented in the protection of human subjects section.

ANSWER: Ok I added their advices about the separation of the coupled dataset from any other data and the VPN connexion 349-353

Lines 215-216: After this authorization, the process of data extraction, exchange, collection, anonymization, etc. started (Figure 2) and the final files were made available for the researchers in October 2017. => This is the typical information that should be found in the data collection section but more practical details are needed.

ANSWER: I think that these practical details relate to the “study flow” section. Or I am wrong? Therefore, I changed the sentence into “this authorizations started the study flow”, otherwise it would have been repetition of the description of the Figure 1 that is made on lines 119-141.