Author's response to reviews

Title: The association between adolescents' health and disparities in school career: a longitudinal cohort study

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Author’s response to reviews: see over
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Dear Mrs. Aguirre,

Thank you for your email of April 29th, stating that you are keen to continue with the submission process for the manuscript ‘The association between adolescents’ health and disparities in school career: a longitudinal cohort study’. You asked us to discuss our study with an ethics committee and send proof that our study does not require ethics approval.

First, we would like to stress that the Steering Committee of the NIVEL Primary Care Database is indeed not an ethics committee and that we did not intend to make it seem so. Approval of the Steering Committee is just necessary as part of the governance structure of the NIVEL Primary Care Database.

Second, we would like to point out that this research has been carried out in accordance with the Dutch Law for the Protection of Personal Data (WBP) and the Law of Agreement on Medical Treatment (WGBO). The NIVEL Primary Care Database has been registered with the Dutch Data Protection Authority and our data were collected and handled according to the guidelines of this Authority.

As we mention in our paper (page 6, lines 134-139), we were legally not obliged to ask ethics approval. According to Dutch legislation, neither obtaining informed consent nor approval by a medical ethics committee is obligatory for observational studies. We have added a reference to the legal article in question (line 137), and we have added the article as an attachment to this cover letter. The legal article does not mention that medical ethics approval is required for our kind of scientific research, and neither does the current European guideline 95/46 EG.

Furthermore, the linkage between the datasets was performed by Statistics Netherlands. This institution is legally allowed to do so in her function as a trusted third party (Statistics Netherlands Act) (see lines 94-96).

We hope that this reply adequately addresses your question and we look forward to your reaction.

In anticipation of your reaction, with kind regards,

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Attachment: Dutch Civil Law, Article 7:458: Data for scientific research

1) Without prejudice to the provisions of Article 7:457 paragraph 1, information about the patient or access to the documents referred to in Article 7:454 may, if requested, be supplied to another person for the purpose of statistics or scientific research in the field of public health without the patient's consent, if:
   a) consent cannot reasonably be requested and guarantees are provided that the patient's privacy will not be inordinately infringed by the conduct of the research;
   b) consent cannot reasonably be requested given the nature and purpose of the research and the care provider has ensured that the data are supplied in such a form as to ensure that they cannot be traced back to individual natural persons.

2) Information may be provided in accordance with paragraph 1 only if:
   a) the research is in the public interest;
   b) the research cannot be conducted without the information in question, and
   c) the patient in question has not explicitly objected against the possibility that information will be provided for this purpose.

3) The fact that information has been provided under paragraph 1 shall be noted in the patient's records.

Dutch Civil Law [http://www.dutchcivillaw.com/civilcodebook077.htm]