Title: From pills to patients: An evaluation of data sources to determine the number of people living with HIV who are receiving antiretroviral therapy in Germany.

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Editorial request:

1.) Ethics statement

Research involving human subjects (including human material or human data) that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Helsinki Declaration (http://www.wma.net/en/30publications/10policies/b3/index.html). A statement to this effect must appear in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate.
2.) Consent statement:
Please state in the Methods section whether written informed consent for participation in the study was obtained from participants or, where participants are children, a parent or guardian.

Dear Editors,

The Robert Koch Institute is the German national public health institute, therefore the Federal Commissioner for Data Protection is the responsible entity for studies which are conducted by the Robert Koch Institute. Information on HIV infection collected in ClinSurv corresponds to the data reported to the RKI according to legal requirements implemented by the national Protection against Infection act (IfSG) of 2001. All patient data collected in ClinSurv are generated during routine care. The German Federal Commissioner for Data Protection therefore waived the need for ethical approval for the ClinSurv study. No written informed consent is required from patients.

We included the above paragraph in the method section (Page 8, Line 172 – 180).

The ClinSurv cohort collects anonymized data from 15 clinical centres on all HIV patients who are in medical care in these centres. We can confirm that this fact was known to the Federal Commissioner for Data Protection when they waived the need for ethical approval for this study.

We hope that the manuscript is now acceptable for publication in BMC Public Health.

We are looking forward to hearing from you.

With best regards

Daniel Schmidt on behalf of all coauthors