BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (http://bmjopen.bmj.com/site/about/resources/checklist.pdf) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

<table>
<thead>
<tr>
<th>TITLE (PROVISIONAL)</th>
<th>Cohort profile: The Lisbon Cohort of Men who have Sex with Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUTHORS</td>
<td>Meireles, Paula; Lucas, Raquel; Martins, Ana; Carvalho, Ana; Fuertes, Ricardo; Brito, João; Campos, Maria; Mendão, Luís; Barros, Henrique</td>
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VERSION 1 - REVIEW

<table>
<thead>
<tr>
<th>REVIEWER</th>
<th>Schmidt, Axel Honorary Research Fellow. Sigma Research, Department of Social &amp; Environmental Health Research, London School of Hygiene and Tropical Medicine, United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>REVIEW RETURNED</td>
<td>02-Jan-2015</td>
</tr>
</tbody>
</table>

GENERAL COMMENTS

This is a well-written article on the methodology and composition of The Lisbon Cohort of Men who have Sex with Men. Community-based cohorts are indeed important in the field of HIV-prevention among MSM. In my view however, the paper has several issues that should be dealt with before publication.

1. The manuscript would benefit from a clearer focus on the methodology of the study and the comparing baseline characteristics of participants. As there seems to be another manuscript under review (“Meireles P, Lucas R, Carvalho C, et al. Incident risk factors as predictors of HIV seroconversion in the Lisbon cohort of MSM: 2011-2014”) that deals with HIV incidence and predictors of seroconversion, the manuscript reviewed here should not try to duplicate these findings. I strongly suggest to delete all sections on HIV incidence and predictors from the current manuscript. It is also not clear how exactly the interviews were performed (Face-to-face interview? Self-administered questionnaire?). It would be nice if a copy of the baseline and follow-up questionnaire would be provided as a supplementary file.

2. Reasons for non-participation should be looked at more closely, particularly as it seems that one strong reason was residing outside Lisbon.

3. The manuscript claims to look at linkage to care among men newly diagnosed with HIV. It does not become clear how this is or will be evaluated.

4. The manuscript claims to deal with behavioural changes over time. However from table 1 it seems that several behavioural variables are not included in the follow up questionnaires (see comments on table 1). The paper must therefore address which changes over time the study can or cannot observe.
Minor issues:

Tables 2, 3, 4, 5, 6, 7, 8
The conceptual difference between “missing” answers that are excluded from the denominator, and the “rather not say” answers that are included in the denominator, is unclear and not explained.

Tables 3, 6, 7, 8
It remains unclear how a multiple choice question can have different numbers of missing answers to each component. There should only be one number for respondents who did not answer the multiple choice question.

Abstract
P3 L6: “New HIV infections” should read “Newly diagnosed HIV infections”. European surveillance systems typically count new diagnoses, while the time of infection is unclear.

P3 L31: “refused to participate” might better read: “did not participate”.

P3 L38f: “Initially” must be added before “HIV-negative”. “MSM-years” must read “person-years of follow up”. The rest of the sentence “likely to be driven …” is not precise enough to be kept in the abstract, and not based on findings presented in this manuscript.

P3 L49: “occurrence” must read “incidence”.

Introduction.
P5 L18: “Incidence” should read “diagnoses” (see above).

P5 L22: “new infections” should read “new diagnoses”.

P5 L27: “HIV/AIDS” is misplaced, as “AIDS” is neither a focus of this paragraph nor of the presented cohort. The sentence should read “In Portugal, like in most EU/EEA countries, the HIV epidemic is concentrated in certain key populations, such as…”

P5 L33f: The statement is incorrect. It must read, for example: “A large internet survey on Portuguese MSM found a prevalence of self-reported HIV infection of 10.9% among participants with a previous HIV test.”

P5 L37: The manuscript refers to an “interview survey”. Do the authors mean “internet survey”? Were the answers based on interviews or on self-administered questionnaires? Is the methodology and the denominator in the two studies comparable (self-reported diagnoses among ever-tested MSM?).

P6 L37: How are trends in secondary HIV prevention (i.e. among the newly diagnosed) going to be monitored, if men with newly acquired HIV drop out of the study?

Cohort description.
P7 L10 /P8 L43: “regardless of nationality”. I would add: “or residence”.

P8 L49: “MSM community” should read “gay community”. “MSM” is a research category and not an identity that is referred to to form communities.

P8 L51: “once located”… Is it now located elsewhere?

P9 L2FF: This section would better be placed under “results” and is in fact a duplication of the content reported there.

P9 L9 and figure 1 “refused to participate” might better read: “declined to participate”.

P9 L13: The manuscript talks about interviews, not questionnaires. The methodology of the interview process must then be described: Who are the interviewers? Is it a face-to-face interview? How might that affect social desirability bias?

P9 L24: “observed” should read “interviewed and tested for HIV” (or: provided with the follow-up questionnaire and tested for HIV).

**Table 1**
- Country of birth is impossible to change. Why is it included in the follow-up questionnaires?
- Role in anal intercourse is likely to change. Why is it not included in the follow-up questionnaires?
- Sexual intercourse with other partners is likely to change. Why is it not included in the follow-up questionnaires?
- Venues to meet occasional partners are likely to change. Why are they not included in the follow-up questionnaires?
- Lubricant and condom use is likely to change. Why are both not included in the follow-up questionnaires?

P11 L14: Is place of residence not queried? This is important, given the large percentage of MSM who decline to take part in the study because they do not live in Portugal. It seems likely that many men declined participation because they do not live in Lisbon.

P12 L52ff: Is appropriately placed here but repeats findings already presented earlier.

P13 L34: age among study participants and non-participants is not normally distributed. Therefore, median age and IQR should be reported here.

P16 L9: Should better read: “said their steady partner was HIV-negative”.

P16 L13: It remains unclear whether the last sexual encounter is meant to be with the steady partner or overall. Also, the time frame for inconsistent condom use should be mentioned here.

P17 L9: See above comment.

Table 6: “Having sex for money”. The direction of the financial transaction is unclear.

P17 L54: The authors should state why they think that 2.3% condom use for oral sex is low (“only”), and whether public health messages for MSM in Portugal recommend condom use for oral sex. Safer sex messages in Europe typically focus on not getting ejaculate into the
mouth, not on using condoms for oral sex.

Table 7: “If he has used alcohol or drugs”, “condoms make him loose erection" - who: the sexual partner or the respondent? // “With a partner that declares undetectable viral load” - the answer does not make sense for non-HIV-diagnosed sexual partners and should only be questioned and reported for sexual encounters with HIV-diagnosed men.

P18 L45: “Lifetime use of alcohol” before or during intercourse. Should be specified - is this about having had a drink before having sex, or is it about having sex while being drunk?

Table 8: Use of alcohol or drugs in the last 12 months should be attributed to the total study population.

Table 10: Diagnoses of STIs should be attributed to the total study population.

Strengths and limitations.
P23 L8: It should be described how “linkage to care” is assessed and analysed.
P23 L25: See above comment (introduction).
P25 L15ff: This whole section seems to be misplaced under “Strengths and limitations”, and should better be placed in the discussion part, as it looks at differences between study populations.
P25 L17: “Table 4” should be “Table 11”.
P25 L29: “estimated by the EMIS study” must read: “estimated by Marcus et al.”
P25 L46 and table 11 (labelled as “4”): age is not normally distributed, particularly due to cut-offs on the lower end. Therefore, median age and IQR should be reported here.
P26 L13: EMIS is short for “European MSM Internet Survey” (The word “Internet” is missing here). In the first line of this table, “EMIS study” should be replaced with “EMIS Portugal”, for clarity.

REVIEWER
Dr. Ulrich Marcus
Department for Infectious Disease Epidemiology, Robert Koch-Institut, Berlin, Germany

REVIEW RETURNED
05-Jan-2015

GENERAL COMMENTS
The manuscript describes the set-up and baseline findings of a prospective cohort of MSM testing for HIV and syphilis at the Checkpoint in Lisbon, a community-based MSM testing and counseling center. This project is an excellent example for a productive cooperation of community-based health promotion projects and public health institutions. Despite the limitations of the study design – an open cohort study – the data collected in this study may prove to become highly useful to monitor the HIV epidemic and the response of MSM to the epidemic in Lisbon. In general, the manuscript is well written and contains many
interesting baseline data of the cohort. Still, a final proof reading by a
native speaker would be recommendable. There are just a few minor
issues which may require revisions or more detailed information.

Specific comments
Ethics/ data protection issues
If I understand correctly, data are collected pseudonymized
(anonymous with a unique name/birth-date-based identifier), and
additional sensitive personal data (e.g. phone-number, email-
address) is collected and stored at checkpoint. What measures are
used to protect these data? Who has access to these data?
p.8-9, 11 Recruitment and follow-up
How are repeat clients identified, or who gets a baseline and who
gets a follow-up questionnaire? By asking the clients, by an
automatic code check?
p.9-11 Questionnaire
Table 1 lists the questions in the baseline and follow-up
questionnaire. While some information collected in the baseline and
not in the follow-up questionnaire is not supposed to change (e.g.
date of birth) or is queried as lifetime prevalence at baseline and
prevalence since last testing in follow-up, some information which
may change over time is only queried in the baseline questionnaire
(e.g. duration of relationship with steady partner; sexual intercourse
with other partners than the steady partner. What are the rationales
for including or not including certain questions in the follow-up
questionnaire?
p.22 Findings to date
There is very little information provided on study participants who
seroconverted during the observation period. Considering the focus
of the manuscript and the fact that the manuscript is already very
long, it may be preferable to delete this paragraph and to publish
these findings in a separate manuscript. Alternatively, more
qualitative and quantitative data on seroconversions, e.g. in form of
an additional table, would be desirable.
p.25-26 Strengths and limitations
Table 4 needs to be re-numbered as Table 11.

VERSION 1 – AUTHOR RESPONSE

Reviewer #1
Reviewer Name: A. J. Schmidt

Comment #1
This is a well-written article on the methodology and composition of The Lisbon Cohort of Men who
have Sex with Men. Community-based cohorts are indeed important in the field of HIV-prevention
among MSM. In my view however, the paper has several issues that should be dealt with before
publication.
1. The manuscript would benefit from a clearer focus on the methodology of the study and the
comparing baseline characteristics of participants. As there seems to be another manuscript under
review ("Meireles P, Lucas R, Carvalho C, et al. Incident risk factors as predictors of HIV
seroconversion in the Lisbon cohort of MSM: 2011-2014") that deals with HIV incidence and
predictors of seroconversion, the manuscript reviewed here should not try to duplicate these findings.
I strongly suggest to delete all sections on HIV incidence and predictors from the current manuscript.
It is also not clear how exactly the interviews were performed (Face-to-face interview? Self-
administered questionnaire?). It would be nice if a copy of the baseline and follow-up questionnaire
would be provided as a supplementary file.

Reply to comment #1
Our first option to include data on HIV Incidence was chosen to comply with the journal's instructions regarding a Cohort profile. Following the reviewer's comment, we have deleted the subsection of “Findings to date” from the abstract and from the “Cohort Description”. This seems even more appropriate now that the paper on HIV incidence and predictors has been accepted for publication and may be referenced.

We have detailed that information is collected using a structured questionnaire during a face to face interview performed by a trained CheckpointLX peer counsellor at each visit (please see Abstract, subsection Participants; and Cohort description, subsection Study procedures, subsection Questionnaire, 1st paragraph). We have translated the original questionnaire to English and added to the submission as a supplementary file.

Comment #2
2. Reasons for non-participation should be looked at more closely, particularly as it seems that one strong reason was residing outside Lisbon.

Reply to comment #2
Reasons for non-participation were asked using close-ended question with possible anticipated answering options. This has limitations for a deeper analysis for which we would need a qualitative study.

As for residing out of Lisbon, this could be an exclusion criterion but we opted not to impose such restriction, since follow-up intervals are not fixed and can be adjusted to participant's convenience. However we can expect a considerable number of men residing outside Lisbon feel that they won't be able to attend follow-up visits and decide not to participate for this reason, but no specific information was collected on this topic.

Comment #3
3. The manuscript claims to look at linkage to care among men newly diagnosed with HIV. It does not become clear how this is or will be evaluated.

Reply to comment #3
We intend, as a long-term objective, to compare different approaches of linkage to care among newly diagnosed with HIV. More specifically we intend to compare linkage to care – measured as the effective utilisation of available services - between those referred to a HIV/AIDS clinic within the cohort context with those linked using alternative procedures (e.g. family doctor) by evaluating: time elapsed between reactive screening test result and scheduling of the first appointment; differences in CD4 cell counts and viral loads at diagnosis; and degree of satisfaction with linkage procedures (please see Introduction, 6th paragraph).

Comment #4
4. The manuscript claims to deal with behavioural changes over time. However from table 1 it seems that several behavioural variables are not included in the follow up questionnaires (see comments on table 1). The paper must therefore address which changes over time the study can or cannot observe.

Reply to comment #4
By mistake, an unfinished version of table 1 was included in the manuscript. The final and correct list of the questions performed at entry and at follow-up visits has been included in the revised manuscript. The study attempts to capture behavioural changes over time and, in fact, behavioural variables that are likely to change are included in the follow-up questionnaire (please see table 1, under subsection Questionnaire).

Comment #5
Minor issues:

Tables 2,3,4,5,6,7,8
The conceptual difference between “missing” answers that are excluded from the denominator, and the “rather not say” answers that are included in the denominator, is unclear and not explained.
Reply to comment #5
We have included in the denominator the “rather not say” answers since they provide valid information reported by the participants. Missing answers are different from those, since no information at all was provided, quite possibly due to the fact that the question was not asked or not recorded in the questionnaire form. We explained this difference in the revised manuscript (please see Statistical procedures under Cohort Description).

Comment #6
Tables 3, 6, 7, 8
It remains unclear how a multiple choice question can have different numbers of missing answers to each component. There should only be one number for respondents who did not answer the multiple choice question.
Reply to comment #6
Each of the answering options for questions presented in tables 3, 6, 7 and 8 (reasons for index test; venue used to meet occasional partners, reasons for not using condom on anal intercourse; alcohol and drug use in the previous 12 months) are collected as variables with four possible answers (No; Yes; Did not know; and Rather not say) and not as mutually exclusive answering options to a single question. This is why the numbers of missing answers are different in each item. We opted to present only the percentage of participants that answered “Yes” in each item; otherwise tables would be too large and readable. As this was unclear in the manuscript, we have added in the revised manuscript an explanatory footnote to tables 3, 6, 7 and 8 (please see tables 3, 6, 7 and 8 under subsection Characteristics of cohort participants).

Comment #7
Abstract
P3 L6: “New HIV infections” should read “Newly diagnosed HIV infections”. European surveillance systems typically count new diagnoses, while the time of infection is unclear.
Reply to comment #7
We agree that is more accurate to say “Newly diagnosed HIV infections” and have followed the reviewer’s suggestion (please see Abstract, subsection Purpose).

Comment #8
P3 L31: “refused to participate” might better read: “did not participate”.
Reply to comment #8
We thank the reviewer for the suggestion and have replaced “refused to participate” with “did not participate” (please see Abstract, subsection Participants).

Comment #9
P3 L38f: “initially” must be added before “HIV-negative”. “MSM-years” must read “person-years of follow up”. The rest of the sentence “likely to be driven …” is not precise enough to be kept in the abstract, and not based on findings presented in this manuscript.
Reply to comment #9
We have, as suggested on comment #1, deleted the subsection of “Findings to date” from the abstract and from the “Cohort Description”.

Comment #10
P3 L49: “occurrence” must read “incidence”.
Reply to comment #10
We have replaced, as suggested, occurrence with incidence because the latter is more specific (please see Abstract, subsection Future plans), even though occurrence can be used with a wider meaning, which comprises both incidence and prevalence (Dictionary of Epidemiology, IEA, 6th ed).
Comment #11
P3 L16 and P4 L5: “Burden of disease” seems to be too broad.
Reply to comment #11
We agree that burden of disease might be too broad given the characteristics of our cohort study and have replace the expression “burden of disease” with “frequency of disease” (Please see Abstract, subsection Purpose; and Strengths and limitations of the study).

Comment #12
Introduction.
P5 L18: “Incidence” should read “diagnoses” (see above).
Reply to comment #12
Incidence was replaced, as suggested, with diagnoses (Please see Introduction, 1st paragraph).

Comment #13
P5 L22: “new infections” should read “new diagnoses”.
Reply to comment #13
We agree that is more accurate to say “new diagnoses” and have followed the reviewer’s suggestion (please see Introduction, 1st paragraph).

Comment #14
P5 L27: “HIV/AIDS” is misplaced, as “AIDS” is neither a focus of this paragraph nor of the presented cohort. The sentence should read “In Portugal, like in most EU/EEA countries, the HIV epidemic is concentrated in certain key populations, such as…”
Reply to comment #14
We have followed the reviewers suggestion (please see Introduction, 2nd paragraph).

Comment #15
P5 L33f: The statement is incorrect. It must read, for example: “A large internet survey on Portuguese MSM found a prevalence of self-reported HIV infection of 10.9% among participants with a previous HIV test.”
Reply to comment #15
We thank the reviewer for the correction. The suggestion has been included (please see Introduction, 2nd paragraph).

Comment #16
P5 L37: The manuscript refers to an “interview survey”. Do the authors mean “internet survey”? Were the answers based on interviews or on self-administered questionnaires? Is the methodology and the denominator in the two studies comparable (self-reported diagnoses among ever-tested MSM?).
Reply to comment #16
By interview survey we mean to briefly describe a cross-sectional survey with information based on interviews where structured questionnaires were administered by trained interviewers. The methodology is not directly comparable to the one of the EMIS; the denominator in both studies is, however, comparable (self-reported diagnoses among ever-tested MSM). We have detailed in the manuscript the differences in the methods and the denominator used for the prevalence estimate (please see Introduction, 2nd paragraph).

Comment #17
P6 L37: How are trends in secondary HIV prevention (i.e. among the newly diagnosed) going to be monitored, if men with newly acquired HIV drop out of the study?
Reply to comment #17
The feature of secondary prevention that we are interested in is early diagnosis of HIV. By following men up to the moment of diagnosis, we are able to monitor the frequency and patterns of HIV testing
uptake among participants enrolled in the cohort, assuming that testing indirectly contributes to reduce the severity of the disease through early detection and prompt treatment (please see Introduction, 6th paragraph).

Comment #18
Cohort description.
P7 L10 /P8 L43: “regardless of nationality”. I would add: “or residence”.
Reply to comment #18
We agree and thank the reviewer for the suggestion, it has been added (please see Cohort Description, 1st paragraph; and subsection Recruitment and follow-up of participants, 1st paragraph).

Comment #19
P8 L49: “MSM community” should read “gay community”. “MSM” is a research category and not an identity that is referred to to form communities.
Reply to comment #19
We agree and have corrected the mistake (please see subsection Recruitment and follow-up of participants, under Cohort description, 1st paragraph).

Comment #20
P8 L51: “once located”… Is it now located elsewhere?
Reply to comment #20
We thank the reviewer for pointing this typo, we have corrected to “since it is located” (please see subsection Recruitment and follow-up of participants, under Cohort description, 1st paragraph).

Comment #21
P9 L2FF: This section would better be placed under “results” and is in fact a duplication of the content reported there.
Reply to comment #21
We intended to give an overall perspective of the recruitment but we agree that it duplicates findings presented in the subsection “Characteristics of enrolled population between April 2011 and February 2014” and have placed the paragraph under the above referred section (please see subsection Characteristics of enrolled population between April 2011 and February 2014 under Cohort description).

Comment #22
P9 L9 and figure 1 “refused to participate” might better read: “declined to participate”.
Reply to comment #22
We thank the reviewer for the suggestion and have replaced “refused to participate” with “declined to participate” throughout the manuscript.

Comment #23
P9 L13: The manuscript talks about interviews, not questionnaires. The methodology of the interview process must then be described: Who are the interviewers? Is it a face-to-face interview? How might that affect social desirability bias?
Reply to comment #23
We have detailed that the method for data collection is a face to face interview performed by a trained CheckpointLX peer counsellor and the instrument used to record data is a structured questionnaire (please see Abstract, subsection Participants; and Cohort description, subsection Study procedures, subsection Questionnaire, 1st paragraph). Social desirability bias is a concern especially when questionnaires are not self-administered. However, we believe that trained peer counsellors are able to reduce such bias with regard to information collected. (Please see Strengths and Limitations, 4th paragraph).
Comment #24
P9 L24: “observed” should read “interviewed and tested for HIV” (or: provided with the follow-up questionnaire and tested for HIV”.
Reply to comment #24
We added the reviewer suggestion (please see subsection Recruitment and follow-up of participants, under Cohort description, 2nd paragraph).

Comment #25
Table 1
- Country of birth is impossible to change. Why is it included in the follow-up questionnaires?
- Role in anal intercourse is likely to change. Why is it not included in the follow-up questionnaires?
- Sexual intercourse with other partners is likely to change. Why is it not included in the follow-up questionnaires?
- Venues to meet occasional partners are likely to change. Why are they not included in the follow-up questionnaires?
- Lubricant and condom use is likely to change. Why are both not included in the follow-up questionnaires?
Reply to comment #25
Country of birth is not included in the follow-up questionnaire; role in anal intercourse, sexual intercourse with other partners, venues to meet occasional partners and lubricant and condom use are included in the follow-up questionnaire; the information on table 1 was incorrect. The correct list of the questions performed at entry and at follow-up visits has been included the revised manuscript (please see table 1, subsection Questionnaire).

Comment #26
P11 L14: Is place of residence not queried? This is important, given the large percentage of MSM who decline to take part in the study because they do not live in Portugal. It seems likely that many men declined participation because they do not live in Lisbon.
Reply to comment #26
We agree that this would be useful information to address reasons for declining participation of men who do not live in Lisbon. However, place of residence is not inquired since our experience suggests that in some cases it may be perceived as too intrusive. (please see Cohort description, subsection Characteristics of enrolled population between April 2011 and February 2014, 1st paragraph).

Comment #27
P12 L52ff: Is appropriately placed here but repeats findings already presented earlier.
Reply to comment #27
Related findings presented earlier were moved to this section and both paragraphs were summarized (please see Characteristics of enrolled population between April 2011 and February 2014 under Cohort description).

Comment #28
P13 L34: age among study participants and non-participants is not normally distributed. Therefore, median age and IQR should be reported here.
Reply to comment #28
We agree that we should have described age using the median, and we have re-analysed data according with the reviewer’s suggestion and re-written the statistical procedures accordingly (please see subsection Statistical procedures; and table 2, subsection Characteristics of enrolled population between April 2011 and February 2014 under Cohort description).

Comment #29
P16 L9: Should better read: "said their steady partner was HIV-negative".
Reply to comment #29
We thank the reviewer for the suggestion and have replaced "had a HIV-negative partner" with "said their steady partner was HIV-negative" (please see Cohort description, subsection Characteristics of cohort participants, 3rd paragraph).

Comment #30
P16 L13: It remains unclear whether the last sexual encounter is meant to be with the steady partner or overall. Also, the time frame for inconsistent condom use should be mentioned here.
Reply to comment #30
It is meant to be with the steady partner, information was added to the paragraph to clarify for the type of partner and the time frame for inconsistent condom use (please see Cohort description, subsection Characteristics of cohort participants, 3rd paragraph).

Comment #31
P17 L9: See above comment.
Reply to comment #31
It is meant to be with an occasional partner, information was added to the paragraph to clarify for the type of partner and the time frame for inconsistent condom use (please see Cohort description, subsection Characteristics of cohort participants, 4th paragraph).

Comment #32
Table 6: "Having sex for money". The direction of the financial transaction is unclear.
Reply to comment #32
We have specified that we meant to describe those who have been paid for sex (please see table 6 presented at subsection Characteristics of cohort participants).

Comment #33
P17 L54: The authors should state why they think that 2.3% condom use for oral sex is low ("only"), and whether public health messages for MSM in Portugal recommend condom use for oral sex. Safer sex messages in Europe typically focus on not getting ejaculate into the mouth, not on using condoms for oral sex.
Reply to comment #33
We agree with the reviewer that our wording was judgemental and have deleted the word "only". There is no consensual benchmark to consider 2.3% of condom use for oral sex as low (please see Cohort description; subsection Characteristics of cohort participants, 5th paragraph).

Comment #34
Table 7: "If he has used alcohol or drugs", "condoms make him loose erection" - who: the sexual partner or the respondent? / "With a partner that declares undetectable viral load" - the answer does not make sense for non-HIV-diagnosed sexual partners and should only be questioned and reported for sexual encounters with HIV-diagnosed men.
Reply to comment #34
Both answers "If he has used alcohol or drugs" and "condoms make him loose erection" are concerning the respondent. According with the reviewer's suggestion we have reported the percentage of men who stated "with a partner that declares undetectable viral load" only among MSM who reported sexual intercourse with HIV-positive men in the previous 12 months (please see table 7 presented at subsection Characteristics of cohort participants).

Comment #35
P18 L45: "Lifetime use of alcohol" before or during intercourse. Should be specified - is this about having had a drink before having sex, or is it about having sex while being drunk?
Reply to comment #35
We did not ask about the amount of alcohol, which means that the frequency presented refers to any alcohol consumption before or during intercourse. This was specified in the manuscript (please see Cohort description, under Characteristics of cohort participants, 6th paragraph). We recognize the limitations of the question, since small consumptions of alcohol are most probably not risky.

Comment #36
Table 8: Use of alcohol or drugs in the last 12 months should be attributed to the total study population.
Reply to comment #36
We have re-analysed data and presented use of alcohol or drugs in the last 12 months as suggested by the reviewer.

Comment #37
Table 10: Diagnoses of STIs should be attributed to the total study population.
Reply to comment #37
We have re-analysed data and presented use of alcohol or drugs in the last 12 months as suggested by the reviewer.

Comment #38
Strengths and limitations.
P23 L8: It should be described how “linkage to care” is assessed and analysed.
Reply to comment #38
Results on linkage to care are not presented in this paper. However, we intend to estimate the rate of linkage to care via CheckpointLX referral by computing the proportion of newly diagnosed MSM who were successfully linked to medical care, i.e. those attending the first medical appointment. As a long-term objective, we also intend to compare different approaches of linkage to care among newly diagnosed with HIV (Please see answer to comment 3 and Introduction, 6th paragraph).

Comment #39
P23 L25: See above comment (introduction).
Reply to comment #39
We have detailed that population-based self-reported HIV infection estimates presented are among MSM with a previous HIV test (please see Strengths and limitations, 2nd paragraph).

Comment #40
P25 L15ff: This whole section seems to be misplaced under “Strengths and limitations”, and should better be placed in the discussion part, as it looks at differences between study populations.
Reply to comment #40
The section on comparisons with previous Portuguese studies was placed under “Strengths and limitations”, as per the journal's guidelines for cohort profiles. Guidelines do not include a Discussion section.

Comment #41
P25 L17: “Table 4” should be “Table 11”.
Reply to comment #41
We thank the reviewer for pointing this typo, it has been corrected.

Comment #42
P25 L29: “estimated by the EMIS study” must read: “estimated by Marcus et al.”
Reply to comment #42
We thank the reviewer for the correction, it now reads as suggested (please see Strengths and
Comment #43
P25 L46 and table 11 (labelled as "4"): age is not normally distributed, particularly due to cut-offs on the lower end. Therefore, median age and IQR should be reported here.
Reply to comment #43
We have re-analysed data according with the reviewer’s suggestion (please see Strengths and limitations, 5th paragraph and table 11).

Comment #44
P26 L13: EMIS is short for “European MSM Internet Survey” (The word “Internet” is missing here). In the first line of this table, “EMIS study” should be replaced with “EMIS Portugal”, for clarity.
Reply to comment #44
We thank the reviewer for pointing this typo, is has been corrected. And “EMIS study” was replaced with “EMIS Portugal” (please see table 11 under Strengths and limitations, 5th paragraph).

Reviewer #2
Reviewer Name Dr. Ulrich Marcus
Institution and Country Department for Infectious Disease Epidemiology, Robert Koch-Institute, Berlin, Germany
Please state any competing interests or state ‘None declared’: I have no competing interests.

Comment #1
The manuscript describes the set-up and baseline findings of a prospective cohort of MSM testing for HIV and syphilis at the Checkpoint in Lisbon, a community-based MSM testing and counselling centre.
This project is an excellent example for a productive cooperation of community-based health promotion projects and public health institutions. Despite the limitations of the study design – an open cohort study – the data collected in this study may prove to become highly useful to monitor the HIV epidemic and the response of MSM to the epidemic in Lisbon.
In general, the manuscript is well written and contains many interesting baseline data of the cohort. Still, a final proof reading by a native speaker would be recommendable. There are just a few minor issues which may require revisions or more detailed information.
Reply to comment #1
We thank for the reviewer’s comment and for the suggestion of a final proof reading by a native speaker. We have followed the suggestion and we believe the quality of the text has improved.

Comment #2
Specific comments
Ethics/ data protection issues
If I understand correctly, data are collected pseudonymized (anonymous with a unique name/birth-date-based identifier), and additional sensitive personal data (e.g. phone-number, email-address) is collected and stored at checkpoint. What measures are used to protect these data? Who has access to these data?
Reply to comment #2
The reviewer has understood correctly, data are in fact pseudonymized and sensitive personal data are collected and stored at CheckpointLX. There are two separate files with the following information: 1. Number of the questionnaire and the phone number and email address; 2. Number of the questionnaire and participant’s unique code (name/birth-date-based identifier). CheckpointLX peer counsellors have access to the first file in order to contact participants; and only Checkpoint’s Technical Coordinator have access to the latter file, protected with a password, which allows for sensitive personal data to be linked to the participant’s unique code.
Comment #3
p.8-9, 11 Recruitment and follow-up
How are repeat clients identified, or who gets a baseline and who gets a follow-up questionnaire? By asking the clients, by an automatic code check?
Reply to comment #3
Repeat clients are identified by asking the client if he has already been invited to enter the cohort. Most clients do not have trouble remembering if they are part of the cohort. However, if a client does not remember being enrolled in the cohort, the peer counsellor usually gives him some external cues, for instance, if he remembers answering a few questions, or giving his birth date and letters of the name to create a code. If he still does not remember, the peer counsellor uses a baseline questionnaire during the interview. As an additional validation procedure we are now implementing a tool that allows the peer counsellor to check for the existence of the participants’ code in the database (please see Cohort description, subsection Recruitment and follow-up of participants, 2nd paragraph).

Comment #4
p.9-11 Questionnaire
Table 1 lists the questions in the baseline and follow-up questionnaire. While some information collected in the baseline and not in the follow-up questionnaire is not supposed to change (e.g. date of birth) or is queried as lifetime prevalence at baseline and prevalence since last testing in follow-up, some information which may change over time is only queried in the baseline questionnaire (e.g. duration of relationship with steady partner; sexual intercourse with other partners than the steady partner). What are the rationales for including or not including certain questions in the follow-up questionnaire?
Reply to comment #4
By mistake, an unfinished version of table 1 was included in the manuscript. The final and correct list of the questions performed at entry and at follow-up visits has been included in the revised manuscript. In fact, information that may change over time is asked in the follow-up questionnaire, namely, duration of relationship with steady partner; sexual intercourse with other partners than the steady partner (please see table 1, under subsection Questionnaire).

Comment #5
p.22 Findings to date
There is very little information provided on study participants who seroconverted during the observation period. Considering the focus of the manuscript and the fact that the manuscript is already very long, it may be preferable to delete this paragraph and to publish these findings in a separate manuscript. Alternatively, more qualitative and quantitative data on seroconversions, e.g. in form of an additional table, would be desirable.
Reply to comment #5
Our first option to include data on HIV Incidence was chosen to comply with the journal’s instructions regarding a Cohort profile. Following the reviewer’s comment, also in accordance with reviewer #1 suggestion, we have deleted the subsection of “Findings to date” from the abstract and from the “Cohort Description”. This seems even more appropriate now that the paper on HIV incidence and predictors has been accepted for publication and may be referenced.

Comment #6
p.25-26 Strengths and limitations
Table 4 needs to be re-numbered as Table 11.
Reply to comment #6
We thank the reviewer for pointing this typo, is has been corrected.
VERSION 2 – REVIEW

REVIEWER
Schmidt, Axel
Sigma Research, Department of Social & Environmental Health Research
London School of Hygiene and Tropical Medicine
United Kingdom

REVIEW RETURNED
24-Feb-2015

GENERAL COMMENTS
This is still a well-written article on the methodology and composition of The Lisbon Cohort of Men who have Sex with Men. Community-based cohorts are indeed important in the field of HIV-prevention among MSM. Before publication, the authors in my view need to pay attention to the following few aspects:

a) The manuscript still claims to look at linkage to care among men newly diagnosed with HIV. The authors need to describe how “linkage to care” was assessed and analysed, or delete the claim from the manuscript.

b) Tables 3, 6, 7, 8
A multiple choice question cannot have different numbers of missing answers to each component, even if the explicit labelling “multiple choice” has now been removed. However removing the label does not change the nature of such question. There can only be one number for respondents who did not answer the multiple choice question, e.g. who did not give any reason for the index test. This applies to all multiple choice questions presented in this manuscript.

Minor issues:

P6 L41: I appreciate the example given for secondary prevention. For balance and clarity, it would be nice to also give an example for primary prevention as well. What is monitored here? Condom use for anal intercourse? Numbers of sexual partners?

Table 1: Employment status is likely to change over time. Why is it not included in the follow-up questionnaire?

Table 7: Again, there is a lack of clarity in Table 7: “If HE has used alcohol or drugs”, “condoms make HIM loose erection” - who does the personal pronoun refer to - the sexual partner or the respondent?

P12 L37f: How is it possible that in an interview with a trained interviewer and a structured questionnaire, no information is recorded (missing answer which is not “rather not say”?). Unless there is evidence that some interviewers forgot to ask certain questions, I cannot see how saying “I rather not give an answer”, or simply not answering the question, can be interpreted as being differently “valid”. The overly large number of missing answers to the question on condom use indicates that this might better be interpreted as “rather not say”.

P18 L56 / P19 L2-3: “and 1262 (57.8) “(...)reported consumption [of alcohol] in the previous 12 months. The most frequently reported
psychoactive substances were alcohol (57.6%)..."

Here the authors report slightly different proportions for the same item (also in the table, the item seems duplicated).

P19 L52f: For clarity, I suggest to re-write this paragraph as follows: "A lifetime history of STI symptoms or diagnoses was reported by 37.2% of respondents; and 9.9% reported STI symptoms/diagnoses in the last 12 months. The most commonly reported STI in the last 12 months was gonorrhoea (2.5%), followed by syphilis (1.7%). 0.5% of respondents reported a lifetime history of hepatitis C diagnosis (none of whom reported injection drug use)." (The text should summarise the table rather than repeat it).

P23 L8: Again, the authors have to describe how "linkage to care" was assessed and analysed, or delete the claim from the manuscript.

P24 L21: Again, the reference to table 4 is wrong. It must read "table 11".

P24 L54: Apart from 24.0 vs. 22.6% in my view is not a difference worth mentioning, "migrant status" is misleading. In both questionnaires, it is about been born outside Portugal. There is no information on the individuals’ legal status.

References:
E.g. Reference No. 6: The authors should pay attention to collective authors like "The EMIS Network". It may not be abbreviated as "Network TE". Reference No. 15 has to read: The EMIS Network.

VERSION 2 – AUTHOR RESPONSE

Reviewer Name A. J. Schmidt

This is still a well-written article on the methodology and composition of The Lisbon Cohort of Men who have Sex with Men. Community-based cohorts are indeed important in the field of HIV-prevention among MSM. Before publication, the authors in my view need to pay attention to the following few aspects:

a) The manuscript still claims to look at linkage to care among men newly diagnosed with HIV. The authors need to describe how "linkage to care" was assessed and analysed, or delete the claim from the manuscript.

Reply to comment a)
The comparison of different approaches of linkage to care is a long-term objective of this cohort. To achieve an acceptable number of events we need a few years of observation. Thus, no assessment was expected during this early stage of the cohort. We agree with the reviewer that such an objective is not appropriately fitted at this level of cohort description and that is why we opted to dropout the reference to linkage to care. We thank the reviewer for pointing out this (please see Introduction, 6th paragraph; Strengths and limitations, 1st and 3rd paragraph).

b) Tables 3, 6, 7, 8
A multiple choice question cannot have different numbers of missing answers to each component, even if the explicit labelling “multiple choice” has now been removed. However removing the label does not change the nature of such question. There can only be one number for respondents who did
not answer the multiple choice question, e.g. who did not give any reason for the index test. This applies to all multiple choice questions presented in this manuscript.

Reply to comment b)

As we tried to present in the 1st set of answers to the reviewers the label multiple choice is not an appropriate designation and that is why we excluded from the text. For each general statement we present a set of different possible explanations to which a Yes/No/Do not know/Rather not say was possible. Under the same general heading "e.g. Reasons for the index test" we listed different statements that could be viewed as independent questions, we admitted that more than one statement could be referred which is legitimate and likely. Then, the final 100% just applies to each statement, they are not cumulative. We opted to present only the percentage of participants that answered “Yes” in each item; otherwise tables would be too heavy. To make it clearer and according to the description of statistical procedures in the Study procedures section we have changed the footnote in the tables 3, 6, 7 and 8 to the following “Percentage of participants that answered “Yes” at each option after excluding missing answers. The remaining participants answered No, Did not know or Rather not say”. We are happy, however, to provide such detailed information in supplementary material if it is the reviewer or editor’s choice.

Minor issues:

c) P6 L41: I appreciate the example given for secondary prevention. For balance and clarity, it would be nice to also give an example for primary prevention as well. What is monitored here? Condom use for anal intercourse? Numbers of sexual partners?

Reply to comment c):

We have added an example of primary prevention monitored in this cohort (please see Introduction, 6th paragraph).

d) Table 1:

-Employment status is likely to change over time. Why is it not included in the follow-up questionnaire?

Reply to comment d):

We fully agree that the documentation of changes in employment status is very important. However we had to make options regarding the extension of the follow-up questionnaire. The consensus among the group (that included peers) was to drop such information. However we will re-evaluate such decision in the future. We thank the reviewer for pointing it out.

e) Table 7: Again, there is a lack of clarity in Table 7: “If HE has used alcohol or drugs”, “condoms make HIM loose erection” - who does the personal pronoun refer to - the sexual partner or the respondent?

Reply to comment e):

For clarity we have changed to pronouns to “the participant” (please see table 7).

f) P12 L37f: How is it possible that in an interview with a trained interviewer and a structured questionnaire, no information is recorded (missing answer which is not “rather not say”?). Unless there is evidence that some interviewers forgot to ask certain questions, I cannot see how saying “I rather not give an answer”, or simply not answering the question, can be interpreted as being differently “valid”. The overly large number of missing answers to the question on condom use indicates that this might better be interpreted as “rather not say”.

Reply to comment f):

This is an interesting point and we agree with the comments and concerns of the reviewer. The numbers of missing answers decreased with time showing that the interviewers got much more used to the process. Yet, we can only attribute the missing answers to the fact that the interviewer did not perform the question or forgot to register the answer, it could also be that in some cases the participants opted not to answer to all and did not clearly stated “rather not to say” and even to
problems in enter data in the database. Although we tend to believe, as the reviewer, that missing answers could be interpreted as “rather not say” we decided to keep the information as collected without making further assumptions.

g) P18 L56 / P19 L2-3: “and 1262 (57.8) “(...)reported consumption [of alcohol] in the previous 12 months. The most frequently reported psychoactive substances were alcohol (57.6%),(...) “

—> Here the authors report slightly different proportions for the same item (also in the table, the item seems duplicated).

Reply to comment g)
It was a typo and it has been corrected. The percentage referred for the consumptions in the previous 12 months is not only for alcohol but for alcohol and drugs (please see please see Characteristics of cohort participants under Study procedures, paragraph 6 and table 8).

h) P19 L52f: For clarity, I suggest to re-write this paragraph as follows: “A lifetime history of STI symptoms or diagnoses was reported by 37.2% of respondents; and 9.9% reported STI symptoms/diagnoses in the last 12 months. The most commonly reported STI in the last 12 months was gonorrhoea (2.5%), followed by syphilis (1.7%). 0.5% of respondents reported a lifetime history of hepatitis C diagnosis (none of whom reported injection drug use).” (The text should summarise the table rather than repeat it).

Reply to comment h):
The paragraph has been re-written as suggested (please see Characteristics of cohort participants under Study procedures, paragraph 7).

i) P23 L8: Again, the authors have to describe how “linkage to care” was assessed and analysed, or delete the claim from the manuscript.

Reply to comment i)
As replied in comment a) we opted to delete the claim to assess linkage to care from the manuscript.

j) P24 L21: Again, the reference to table 4 is wrong. It must read “table 11”.

Reply to comment j):
We thank the reviewer for pointing out this typo, we have corrected the reference to table 11 (please see Strengths and limitations, 5th paragraph).

k) P24 L54: Apart from 24.0 vs. 22.6% in my view is not a difference worth mentioning, “migrant status” is misleading. In both questionnaires, it is about been born outside Portugal. There is no information on the individuals’ legal status.

Reply to comment k):
We have removed the reference to the differences regarding the country of birth between the two studies (please see Strengths and limitations, 5th paragraph and table 11).

l) References:
E.g. Reference No. 6: The authors should pay attention to collective authors like “The EMIS Network”. It may not be abbreviated as “Network TE”. Reference No. 15 has to read: The EMIS Network.

Reply to comment l)
We thank the reviewer for pointing out this typo, it has been corrected (please see reference 6).

In addition to the reviewers suggestions we have made the following corrections to the manuscript:
1. We added a percentage that was missing in table 10 along with the numbers of participants responding “do not know” to the history of gonorrhoea;
2. We changed the reference to the estimate of prevalence of HIV infection in a previous cross-sectional study from the reference 16 (Dias S, Mendão L, Gama A, Barros H. How to access vulnerable and hard-to-reach populations? Methodological challenges in HIV and STIs
epidemiological and behavioural research with sex workers [abstract]. European Journal of Epidemiology 2012(27):S1-S197 to a personal communication (Gama A 2013, personal communication) as this is more accurate and consistent with reference used in the Introduction (please see Strengths and limitations, 2nd paragraph);
3. We corrected the percentage of participants who reported homosexual identity, university degree and a previous HIV test in table 11 and in the 5th paragraph of Strengths and limitations;
4. We added the meaning of abbreviations to the name of the authors in the reference 5.
The Lisbon Cohort of men who have sex with men

Paula Meireles, Raquel Lucas, Ana Martins, Ana Cláudia Carvalho, Ricardo Fuertes, João Brito, Maria José Campos, Luís Mendão and Henrique Barros


Updated information and services can be found at: http://bmjopen.bmj.com/content/5/5/e007220

**Supplementary Material**
Supplementary material can be found at: http://bmjopen.bmj.com/content/suppl/2015/05/12/bmjopen-2014-007220.DC1

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