PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Inconsistent condom use by male clients during anal intercourse with occasional and regular female sex workers (FSWs): Survey findings from southern states of India
AUTHORS	Ramanathan, Shreena; Nagarajan, Karikalan; Ramakrishnan, Lakshmi; Mainkar, Mandar; Goswami, Prabuddhagopal; Yadav, Diwakar; Sen, Shrabanti; George, Bitra; Rachakulla, Hari; Subramanian, Thilakavath; Paranjape, Ramesh

VERSION 1 - REVIEW

REVIEWER	Souradet Shaw University of Manitoba
	Canada
REVIEW RETURNED	27-May-2014

GENERAL COMMENTS	Although the statistical methods chosen are generally appropriate, I think there is a fundamental lack of clarity about the distribution of HAI across states/districts. Although the authors claim that controlling for geography was unnecessary because of application of the two-stage cluster sampling design was uniform across study sites, there is no reason to suspect that HAI was equally distributed across states/districts (and in fact, I would be surprised if it was homogeneous across the study sites). Thus, the authors should at the very least present the results of their analyses with district/state in their models.
	There was also no mention of an attempt at sub group analyses or interactions. For example, the number of FSWs and number of sex acts seems like a relationship worthy of more exploration. The authors need to comment on why they chose not to perform any subgroup analyses.
	Additionally, the authors need to make more clear the fact that they are analysing only a small fraction of their clients; that is, the 12% who reported HAI.
	Generally, a well-written and researched paper on a topic where there is a gap in knowledge. In addition to issues regarding understanding (and controlling) for heterogeneity in distribution of HAI by district/state, I think the authors need to really expand upon the gendered power dynamics in India, and the lack of choice women have with HAI. An expanded condom and lubrication distribution program, although a nice start, is unlikely to change the sexual proclivities of clients.

REVIEWER	Martine Collumbien

	Senior Lecturer
	London School of Hygiene and Tropical Medicine
REVIEW RETURNED	18-Jun-2014
GENERAL COMMENTS	My answers to this check list are partly arbitrary because although study design might be appropriate the analysis plan has some omissions that need to be rectified (nowhere to indicate this) - also first study objective would ideally become a little more specific (see overall comments) and this has implications for discussion
	This is a welcome paper attempting to summarize the current prevalence of anal intercourse and investigate correlates of inconsistent condom use. There is growing interest in the topic globally and therefore presenting correlates of anal intercourse itself, as well as adding some additional predictors of inconsistent condom use would greatly improve the contribution this paper makes. In more detail:
	1. The paper makes the point that condom use for anal intercourse is low in heterosexual commercial sex and that this needs more attention in interventions targeted at FSWs and their clients. However an important predictor of condom use for anal sex may be condom use for vaginal sex, and the analysis would be much more powerful if it showed levels of use for vaginal sex too. Suryawanshi (2013) shows that condom use for all acts (including vaginal and anal) varies greatly between the three states; the reporting of the practice of anal intercourse itself also varies. Given this variability it would be good to present levels of anal intercourse in the 3 states together with average condom use for vaginal and anal intercourse separately. The table could be similar to Table 1 where the profile of men reporting anal sex is compared to those who do not report it +
	 add state too. 2. When building the model for inconsistent condom use for anal sex obvious predictors to add are condom use for vaginal sex and state. 3. In Table 2, the reader would be interested to see a column showing the levels of inconsistent condom use in each subcategory and add another column with the crude ORs, as that makes the analyses much more transparent. 4. In discussion p13 line 16 the reference to 'our' study reporting low levels of anal sex in commercial encounters is a little confusing – does this refer to reports by FSWs in IBBA or to clients data 5. In your discussion on older men been less likely to use condoms (p 13 third para) you may want to hypothesize that this might be caused by the fact that ability to maintain erections is inversely correlated with age 6. Under limitations when discussing social desirability Lam not sure
	6. Under limitations when discussing social desirability I am not sure that clients have a reason to underreport condom use – and although anal sex is certainly stigmatised among FSW I am not sure whether this is similar for men. If, as the global discourse seems to suggest, pornography may lead men to experiment more, it may well be possible they start over-reporting? There is probably no evidence on this. One other limitation of your analysis (or rather your data) is that you have no information on violence/coercion and you do point out in your introduction that this is an important correlate

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

Reviewer Name: Souradet Shaw, Institution and Country University of Manitoba, Canada Please state any competing interests or state 'None declared': Non declared

Comment 1: Although the statistical methods chosen are generally appropriate, I think there is a fundamental lack of clarity about the distribution of HAI across states/districts. Although the authors claim that controlling for geography was unnecessary because of application of the two-stage cluster sampling design was uniform across study sites, there is no reason to suspect that HAI was equally distributed across states/districts (and in fact, I would be surprised if it was homogeneous across the study sites). Thus, the authors should at the very least present the results of their analyses with district/state in their models.

Response: We appreciate the reviewers concern and have added the distribution of HAI across states in the results section (page 11, line 5,6). However, district wise distribution is not presented owing to the very small numbers as also highlighted by the reviewer in the next comments. As suggested, we also did the analysis including the state/district variables but the odds ratio and standard error was showing extreme values and so the variable was excluded from the model and the results presented earlier have been retained.

Comment 2: There was also no mention of an attempt at sub group analyses or interactions. For example, the number of FSWs and number of sex acts seems like a relationship worthy of more exploration. The authors need to comment on why they chose not to perform any subgroup analyses. Response: We agree with the reviewer that the association between the number of FSWs and number of sex acts is worthy of more exploration. Since only a small fraction of the clients reporting anal sex were analyzed we did not attempt at any sub-group analysis, which would necessitate more extrapolation of findings. We could explore the possibility of a short paper on sub-group analysis separate from this article.

Comment 3: Additionally, the authors need to make more clear the fact that they are analysing only a small fraction of their clients; that is, the 12% who reported HAI.

Response: In the limitation section we have now added a few sentences where we have clearly stated that analysis included only those clients having reported anal sex which is a small fraction of the total number of clients (page 15, line 19-20).

Comment 4: Generally, a well-written and researched paper on a topic where there is a gap in knowledge. In addition to issues regarding understanding (and controlling) for heterogeneity in distribution of HAI by district/state, I think the authors need to really expand upon the gendered power dynamics in India, and the lack of choice women have with HAI. An expanded condom and lubrication distribution program, although a nice start, is unlikely to change the sexual proclivities of clients. Response: We agree with the reviewers comments that an expanded condom and lubrication distribution program is unlikely to change the sexual proclivities of clients. In the manuscript the discussion on gendered power dynamics in India and the lack of choice women have with HAI has been included (page 15, lines 6-11).

Reviewer 2 Reviewer Name: Martine Collumbien, Institution and Country Senior Lecturer, London School of Hygiene and Tropical Medicine Please state any competing interests or state 'None declared': Non declared

My answers to this check list are partly arbitrary because although study design might be appropriate the analysis plan has some omissions that need to be rectified (nowhere to indicate this) - also first study objective would ideally become a little more specific (see overall comments) and this has implications for discussion

This is a welcome paper attempting to summarize the current prevalence of anal intercourse and investigate correlates of inconsistent condom use. There is growing interest in the topic globally and therefore presenting correlates of anal intercourse itself, as well as adding some additional predictors of inconsistent condom use would greatly improve the contribution this paper makes. In more detail:

Comment 1: The paper makes the point that condom use for anal intercourse is low in heterosexual commercial sex and that this needs more attention in interventions targeted at FSWs and their clients. However an important predictor of condom use for anal sex may be condom use for vaginal sex, and the analysis would be much more powerful if it showed levels of use for vaginal sex too. Suryawanshi (2013) shows that condom use for all acts (including vaginal and anal) varies greatly between the three states; the reporting of the practice of anal intercourse itself also varies. Given this variability it would be good to present levels of anal intercourse in the 3 states together with average condom use for vaginal and anal intercourse separately. The table could be similar to Table 1 where the profile of men reporting anal sex is compared to those who do not report it + add state too. Response: We agree with the reviewers comments and have added the vaginal sex condom use

proportion (state wise) in our result section (page 11, lines 7-11). We have avoided presenting it as part of Table-1 since that would necessitate the discussion part to elaborate on vaginal sex- condom use which is not the prime focus of the paper. In the result section, state wise vaginal sex – condom proportions have been mentioned so that the reader can make comparison.

Comment 2: When building the model for inconsistent condom use for anal sex obvious predictors to add are condom use for vaginal sex and state.

Response: We agree with the reviewer comments that obvious predictors to add are condom use for vaginal sex and state. We did the analysis including the state variable but the odds ratio and standard error was showing extreme values and so the variable was excluded from the model. Similarly, the variable for condom use during vaginal sex (for both occasional and regular sex partner) was also included in the analysis. But the findings showed that the variable for condom use during vaginal sex workers, was having high collinearity with dependent variable leading to an extreme odds value (.001) which is uninterpretable. The addition of vaginal sex condom use was also impacting the significance of other independent variables due to its high collinearity with dependent variable. And so the variable was avoided from the model and the results presented earlier have been retained.

Comment 3: In Table 2, the reader would be interested to see a column showing the levels of inconsistent condom use in each subcategory and add another column with the crude ORs, as that makes the analyses much more transparent.

Response: We agree with the reviewer and have added the crude odds ratios in table 2 (page 20).

Comment 4: In discussion p13 line 16 the reference to 'our' study reporting low levels of anal sex in commercial encounters is a little confusing – does this refer to reports by FSWs in IBBA or to client's data

Response: We thank the reviewer for the comment. As stated in the below paragraph we compared the estimated prevalence from the current analysis with reports by FSWs in IBBA and other studies. The revision in the paragraph is as below (page 13, lines 1-6):

"In the absence of comparable estimates on anal intercourse from client surveys in India, we examined the estimates available from studies on FSWs.13,14,18 It was apparent that there is a high demand for anal sex. When compared with the prevalence reported by previous FSW studies, the prevalence estimated in the current analysis seems to be much lower. Anal sex is certainly stigmatized among FSWs and they have a reason to under report condom use. However, we don't know if it is similar for men and this was not measured and is a major limitation".

Comment 5: In your discussion on older men been less likely to use condoms (p 13 third para) you may want to hypothesize that this might be caused by the fact that ability to maintain erections is inversely correlated with age.

Response: We thank the reviewer for the suggestion. As suggested, we have added this important explanation in the discussion section.

The addition in the discussion section is as below (page 13, lines 7-15):

"The finding that older clients are at a higher risk of inconsistent condom use has been reported previously. Inconsistent condom use during vaginal intercourse with FSWs was found to be significantly associated with older clients.2 The average age of marriage for Indian men is documented to be 26 years, and a majority of men (clients of FSWs) in this sample were married. A possible explanation for this risky behavior among older men could be the need to fulfill sexual desires or experimentation, followed by the belief that paying for sex would be less troublesome and more entertaining than sexual involvement with a non-sex worker.28 It could also be plausible that inability of the older men to maintain erections may have resulted in inconsistent use of condoms during anal sex when compared to younger men."

Comment 6: Under limitations when discussing social desirability I am not sure that clients have a reason to underreport condom use – and although anal sex is certainly stigmatized among FSW I am not sure whether this is similar for men. If, as the global discourse seems to suggest, pornography may lead men to experiment more, it may well be possible they start over-reporting? There is probably no evidence on this. One other limitation of your analysis (or rather your data) is that you have no information on violence/coercion and you do point out in your introduction that this is an important correlate.

Response: We thank the reviewer for the comments. The limitation section is revised as below (page 15,16, 14-22; 1-4):

"Our study has its limitations. For one, both anal intercourse and condom use are self-reported measures and may, therefore, be influenced by the social desirability bias. As indicated by previous research, the social desirability bias gives rise to the possibility of underreporting. Given the difficulty in evaluating the magnitude of underreporting, we must be cautious in concluding that anal intercourse is practiced at relatively low rates among this population. Another limitation is that the analysis included only those clients having reported anal sex which is a small fraction of the total number of clients. Further, we did not have information on anal intercourse with regular female partners to establish concurrency or multidirectional risk during anal intercourse. Also, the survey did not gather information on violence/coercion during anal sex. Future studies need to address these gaps. In addition, qualitative studies are needed to better understand the context in which anal intercourse occurs. In spite of these limitations, this is one of the first studies to document for the clients of FSWs the practice of anal intercourse and the correlates of condom use during anal intercourse."

VERSION 2 – REVIEW

REVIEWER	Martine Collumbien London School of Hygiene and Tropical Medicine
REVIEW RETURNED	21-Aug-2014

GENERAL COMMENTS	Some of the clarifications given in response to earlier comments
	seem to raise more issues than they solve.
	The authors indicate that in Andhra Pradesh, 75.5% of clients have
	used condoms for anal sex with sex workers. Is this really the case?
	This seems an enormous success and we need to learn why this is,
	especially as only 40% seem to be using it for vaginal sex amongst
	this restricted sample of men- is this an error? if it is not, why is the
	entire paper concluding that condom use is low everywhere. Yes in
	Tamil Nadu and Maharashtra but no in Andhra Pradesh. This simple
	observation seems more worthwhile reporting and exploring than
	just ignoring the state wise differences and limiting the model to
	variables that do not seem to give extreme values I do not agree
	with the author's response to comment 2 - now that the authors have
	clarified the great state-wise variation in outcomes, the stated
	reason for leaving out state from the model is that the ORs give
	extreme values. Surely this is not valid! Indeed state (or state-
	specific interventions?) seems to be the major predictor of condom
	use in anal sex. Instead this should call for running the models
	separately by state, or at least separately for Andhra Pradesh versus
	the two other states (or not running the model at all). The editors
	may choose to call for specialist statistical review to adjudicate on
	this.
	Note that the observation of 75% condom use during anal
	intercourse in Andhra Pradesh now completely contradicts the key
	message of the paper!
	The authors' corrections in reply to Comment 4 are not very clear.
	"In the absence of comparable estimates on anal intercourse from
	client surveys in India, we examined the estimates available from
	studies on FSWs.13,14,18" It would be useful to state the range of
	estimates given in these papers. Note though that all 3 papers are
	from AP and as illustrated this seems a very different context than
	the other two states. "It was apparent that there is a high demand for
	anal sex." How high? "When compared with the prevalence reported
	by previous FSW studies" you mean the papers mentioned above?
	"the prevalence estimated in the current analysis seems to be much
	lower" meaning that clients report less anal sex than sex workers?
	"Anal sex is certainly stigmatized among FSWs and they have a
	reason to under report condom use" I would assume they would
	under-report anal sex, but what would the reason be for under-
	reporting condom use? "However, we don't know if it is similar for
	men and this was not measured and is a major limitation" Not clear
	what "it" is.
	It seems incorrect to state that "the analysis included only those
	clients who having reported anal sex which is a small fraction of the
	total number of clients" is "another limitation". It is just a reality that
	you restrict the analyses to those engaging in anal sex
	The key messages of the paper need to be changed, and it would be
	worthwhile to explore why condom use was so much higher in AP
	than in the other two states.

VERSION 2 – AUTHOR RESPONSE

Reviewer Name: Martine Collumbien

Institution and Country: London School of Hygiene and Tropical Medicine Please state any competing interests or state 'None declared': None declared

Comment 1

Some of the clarifications given in response to earlier comments seem to raise more issues than they solve. The authors indicate that in Andhra Pradesh, 75.5% of clients have used condoms for anal sex with sex workers. Is this really the case? This seems an enormous success and we need to learn why this is, especially as only 40% seem to be using it for vaginal sex amongst this restricted sample of men- is this an error? if it is not, why is the entire paper concluding that condom use is low everywhere. Yes in Tamil Nadu and Maharashtra but no in Andhra Pradesh. This simple observation seems more worthwhile reporting and exploring than just ignoring the state wise differences and limiting the model to variables that do not seem to give extreme values ... I do not agree with the author's response to comment 2 - now that the authors have clarified the great state-wise variation in outcomes, the stated reason for leaving out state from the model is that the ORs give extreme values. Surely this is not valid! Indeed state (or state-specific interventions?) seems to be the major predictor of condom use in anal sex. Instead this should call for running the models separately by state, or at least separately for Andhra Pradesh versus the two other states (or not running the model at all). The editors may choose to call for specialist statistical review to adjudicate on this. Note that the observation of 75% condom use during anal intercourse in Andhra Pradesh now completely contradicts the key message of the paper!

Response: We thank the reviewer for the comments. As pointed out there was an error in the reporting of the state wise proportions. We have now revised the proportions and the correct proportions are presented. Earlier we had reported the column proportion in Table-1 which now has been revised to give the row percentages with state variable as the denominator. The focus of the current paper is an aggregate analysis based on data available from clients of sex workers in southern states and therefore state wise segregated analysis is not presented. The number of clients reporting anal sex varies widely in the three states and the proportion range from 18.9% to 6.5%. Within this sample when analyzing the condom use practice independently in the three states the numbers get even smaller. The exact numbers and proportions of anal sex and condom use are presented in a new Figure -2 which has been added as part of the results section for clarity.

Comment 2

The authors' corrections in reply to Comment 4 are not very clear. "In the absence of comparable estimates on anal intercourse from client surveys in India, we examined the estimates available from studies on FSWs.13,14,18" It would be useful to state the range of estimates given in these papers. Note though that all 3 papers are from AP and as illustrated this seems a very different context than the other two states. "It was apparent that there is a high demand for anal sex." How high? "When compared with the prevalence reported by previous FSW studies" you mean the papers mentioned above? "the prevalence estimated in the current analysis seems to be much lower" meaning that clients report less anal sex than sex workers? "Anal sex is certainly stigmatized among FSWs and they have a reason to under report condom use" I would assume they would under-report anal sex, but what would the reason be for under-reporting condom use? "However, we don't know if it is similar for men and this was not measured and is a major limitation" Not clear what "it" is.

Response: We thank the reviewer for the comments. As suggested, we have added the range of estimates from the cited papers. We agree the context in all three states is different but most papers on FSW and their clients are from the state of Andhra Pradesh or Karnataka and there is paucity of published literature on clients of sex workers from the other states. We have revised the mentioned section for better clarity.

Comment 3

It seems incorrect to state that "the analysis included only those clients who having reported anal sex which is a small fraction of the total number of clients" is "another limitation". It is just a reality that you restrict the analyses to those engaging in anal sex The key messages of the paper need to be changed, and it would be worthwhile to explore why condom use was so much higher in AP than in the other two states.

Response: We agree with the reviewers comment and have removed the sentence from the limitation section. As we mentioned in our reply for first comments, the focus of the current paper is an aggregate analysis based on data available from clients in southern states and therefore an separate exploration of Andhra Pradesh state is not presented.

VERSION 3 - REVIEW

REVIEWER	Martine Collumbien LSHTM, UK
REVIEW RETURNED	01-Oct-2014

GENERAL COMMENTS	The first sentence of your abstract "Recent studies from India have documented varying estimates of self-reported anal intercourse (ranging 3% to 80%) by female sex workers (FSWs)." This seems at odds with what you say in the discussion "In the absence of comparable estimates on anal intercourse from client surveys in India, we examined the estimates available from studies on FSWs13 14 18 28and the reported prevalence ranged from 11.9% to 22.0%" Then, it seems confusing to say that "When compared with the prevalence reported by in these previous FSW studies, the prevalence estimated in the current analysis seems to be much lower" Yet is it not 12% of clients reporting it? That seems to match quite well?
	So estimates either in abstract or discussion need to be clarified.

VERSION 3 – AUTHOR RESPONSE

We thank the reviewer for pointing out this discrepancy in our manuscript. We have rechecked our references and have altered that estimates in both abstract and discussion part. The corresponding sentences too have been altered.