RESPONSE TO REVIEWERS

We are deeply indebted to the reviewers for their time and their thoughtful comments. We have responded to each comment in **bold** type, below.

Reviewer(s)' Comments to Author:

Reviewer: 1

Comments to the Author
This brief report documents an estimate of HIV incidence among young, black MSM attending a testing program in Pittsburgh, PA, a mid-size US city. The authors find a very high point estimate for HIV incidence that is on-par with other estimates recently reported in other, large US cities. The data are sparse and the estimates are unstable, but these findings belong in the literature as further documentation of the extent of the HIV epidemic for YBMSM across geographic contexts. A few point for revision are described below.

Major comments:

- Aside from the primary likelihood that these YBMSM participants were representative of their community that is experiencing very high HIV incidence, there is the possibility that these participants were a particularly high-risk subset of men. No behavioral or social determinants data on these participants are presented. I'm not sure of the extent of this data collection in the testing program, but any presentation of behavioral risk (ie: CAI, partner number, substance use) or sociodemographic data would help to place the sample in context and help to assess the potential for selection bias.

We appreciate this comment, which was raised in slightly different language by the other two reviewers. We added the following sentence to the Methods section to explain our approach: "Post-hoc analyses assessed rates of condomless anal intercourse (CAI), condomless vaginal intercourse (CVI), and sex with HIV-positive partners, using self-reported data collected during participants' most recent HIV testing and counseling sessions."

We have provided an additional paragraph in the Results section discussing behavioral data reported during HIV testing and counseling: "At their most recent test, 23 (59.0%) reported condomless anal intercourse (CAI) with a male partner, and three (7.7%) reported condomless vaginal intercourse with a female. Three individuals (7.7%) reported at most recent test having had sex with an HIV-positive male partner, while 11 (28.2%)

reported being unsure whether any male sexual partners were HIV-positive. Twenty-four separate ZIP codes were represented by participants; 96% were from the Pittsburgh region (data not shown)."

We have also added two sentences to the Discussion section that attempt to put the behavioral risks reported by the YBMSM in this sample into context: "While the proportion of YBMSM in this sample reporting condomless anal intercourse (59.0%) appears high, the rate reported here is lower than in other recent studies demonstrating that large majorities of MSM, including those who are Black, engage in CAI.[8] Second, sexual behaviour data collected during rapid HIV testing events is streamlined in this region; secondary data analysis offers few opportunities to analyse risk or protective correlates, such as partner number or PrEP/nPEP use. In addition, participants disclose sexual behavior data to test counselors, which may heighten social desirability bias in responses. This suggests that the YBMSM in this sample are not engaging in risky sexual behavior at higher rates than their counterparts in other U.S. locales."

We also added sentences to the limitations section discussing how behavioural data are collected during HIV testing and counseling: "Second, sexual behaviour data collected during rapid HIV testing events is streamlined in this region; secondary data analysis offers few opportunities to analyse risk or protective correlates, such as social determinants, partner number or PrEP/nPEP use. In addition, participants disclose sexual behavior data to test counselors, which may heighten social desirability bias in responses."

Minor comments:

- The sentence "Despite worrisome background data, surprisingly few studies have attempted to calculate HIV incidence rates among young Black MSM in the U.S." has a bit of a subjective tone and feels a mischaracterization of the recent history of the US epidemic. In response to strong signals in surveillance data and small prevalence studies in the early 2000s, a number of prospective studies focusing on this most at-risk population were began in the late 2000s. Due to the nature of these studies, the results take years to come in and are now becoming more available. Thus I agree that this population and we researchers want and should have more incidence data, but I think this sentence mis-represents the situation as a lack of attention to the issue.

Thank you for this comment. We have made changes to the text so that it now reads: "HIV incidence studies are resource-intensive and, by their nature, lengthy; it may be for these reasons that the literature so far contains only a small number that have calculated HIV incidence rates among young Black MSM in the U.S., though several currently funded studies may soon provide further data."

In response to this comment, we also added the following sentences to the introduction to better detail this manuscript's methodological contribution: "However, HIV testing and counseling programmes exist across the U.S., and several new funding initiatives from the Centers for Disease Control and Prevention have encouraged a focus on HIV testing provided specifically to YBMSM populations. By utilizing data already being collected in sites such as these, public health programmes can augment existing HIV epidemiology."

- The Discussion implies that the NHAS and/or the prevention community has overlooked mid-sized cities, but that is an unsubstantiated claim. It feels like a straw-man argument in the absence of data.

We agree with this comment, and have removed this sentence from the Discussion. We added an additional clause (italicized below) to an existing sentence to clarify this manuscript's contribution: "These data demonstrate that even cities with low overall HIV prevalence rates can be settings in which very high HIV incidence rates can exist among vulnerable populations such as young Black MSM, *and that community-based organizations implementing regular HIV testing can contribute valuable incidence information to locally supplement any existing regional or state data."*

- Remove the sentence "We could not incorporate data from participants whose first HIV antibody test results onsite were positive (resulting in the omission of the majority of positive results).", because by definition prevalent infections are never expected to be included in incidence analyses.

We agree, and have removed this sentence.

- Reference 7 refers to a CROI presentation that has been since published in its final form in: Sullivan PS, Rosenberg ES, Sanchez T, Kelley CF, Luisi N, Cooper HL, DiClemente R, Wingood G, Frew PM, Salazar LF, del Rio C, Mulligan MJ, Peterson JL. Explaining Racial Disparities in HIV Incidence in a Prospective Cohort of Black and White Men Who Have Sex With Men in Atlanta, GA: A Prospective Observational Cohort Study. Annals of Epidemiology. 2015 June. 25(6): 445–454

Thank you, we have revised this reference.

Reviewer: 2

Comments to the Author
The authors report on a small study of HIV incidence among young black MSM in a US city. These are critical data and the authors appropriately point out that there are few recent published reports of HIV incidence in this population. While the analysis is important, the sample size is quite small, the precision of the HIV incidence estimate is low, and the authors overstate their

results throughout. This short report would benefit from some editing as well better contextualizing this small study in the larger scheme of HIV prevention and control.

Abstract: The Objective section is much too long and is a cut and paste from the background section of the submission. This should not just repeat the main study, but synthesize and summarize.

We agree, and have rewritten the Objectives section so that it summarizes the key objectives of this study: "Objectives: To calculate HIV incidence in a naturally-occurring cohort of young (13-29 year old) Black men who have sex with men (YBMSM) accessing repeated HIV-antibody testing in a mid-size city in the United States. To establish a method for HIV incidence calculation that community-based organizations can easily use in order to supplement any existing local or regional epidemiological data on key populations."

Also it is not clear what is meant by a "naturally-occurring" cohort Intro and Methods:

We agree with the reviewer, and have added the following information to the Methods section: "For this secondary data analysis, we considered this group of YBMSM to have constituted a naturally-occurring cohort, e.g. a cohort that developed from a group of individuals who utilized the safe community space provided by Project Silk and who elected to receive regular HIV testing there."

Throughout the paper the county and city have been XXXXXX out. This is odd and made me initially think that this submission was still a draft. It is hard to contextualize the findings without knowing the specific city in which the study took place. This is particularly important as one of the major points of the study was that even in cities with a low prevalence, incidence may be high.

We apologize; we think that we confused both the editor and the reviewers by using XXXX as a way to blind the manuscript during peer review. The County and project names have now been restored.

P.5 the paper states that the overall HIV prevalence of the XXXXX city is 0.23%. What is the reference for this estimate and how was prevalence determined?

This is based on CDC surveillance data and published at aidsvu.org. We did not originally reference this due to the journal's reference limit, but we hope the editor will make an exception as we have now added this reference in response to the reviewer's comment.

p.6, the sample section states “Upon each daily entry…” It is not clear what was entered daily. This needs to be better explained.

We agree, and have reworked the beginning of the sentence (italicized below): “*Every day that a participant enters the space, he or she logs into* an electronic, password-protected intake system to request services offered onsite, including HIV and STI testing, linkage to medical care, and broad-spectrum social services.”

Results:
The n for this study was quite small (39). The HIV incidence estimated has a large 95% CI. What was the HIV prevalence among the black MSM enrolled in the cohort? This would help to contextualize the incidence estimates.

In response to this question, we have added the overall seroprevalence rates to the Discussion section to better contextualize our incidence findings: “Overall seroprevalence (including previous positives) among YBMSM at this site has averaged above 20%, with a new diagnosis rate of over 6% for HIV test events.”10

Discussion: The authors significantly overstate the importance of the finding based on 39 men enrolled in their cohort. While the analysis is useful and important, it is small and represents one study. The discussion should be edited to better communicate the findings in terms of the limitations.

In response to the reviewer’s comment, we made several additions to the limitations setting, adding the following two sentences: “First, we were unable through existing data-sharing protocols to identify and include any individuals who tested HIV-negative at our site but who later seroconverted at other HIV testing sites. Second, sexual behaviour data collected during rapid HIV testing events is streamlined in this region; secondary data analysis offers few opportunities to analyze risk or protective correlates, such as social determinants, partner number or PrEP/nPEP use.” In addition, we added clauses (italicized) to the next sentence to better clarify regional limitations: “Participants receiving HIV-antibody testing onsite are offered risk assessments, STI testing, sexual health counseling, and access to biobehavioural interventions, as well as social support, social service, and social capital initiatives intended to facilitate HIV risk reduction; results may not be generalizable to young Black MSM *in the region* who do not have these opportunities*, or to YBMSM outside the region*.”

Reviewer: 3

Comments to the Author
The authors estimate the incidence of an HIV diagnosis in a convenience cohort of young MSM accessing services in community health space.

Primary concerns
1) The use of anonymized location is unusual and I was confused by the XXXXs and thought it was a typo. I'm not sure of the rationale of using Xs since the project and location can be determined by looking at the references (e.g., ref 9's title is "…Project Silk…"). If there is a strong rationale for anonymizing, suggest stating that in the methods section. Also, the PA DoH is named on page 7—suggest removing if you are trying to be anonymous.

See our comment above; we were trying only to blind the manuscript for peer review.

2) I still don't have a clear sense of who participated in Project X so it's difficult to interpret the observed diagnosis rate. Additionally, findings are based on only 39 participants! I would suggest downplaying the estimated incidence given the wide CI and instead focus on the methodology, use of programmatic data, etc.

We agree wholeheartedly, and have added a number of clauses and inserted sentences to the introduction and discussion to note the limitations and highlight the methodology. In the introduction, we have added the following sentence to describe the population that utilizes Project Silk: "This population is diverse, including students, House and Ball Community members, artists and designers, homeless and runaway youth, and their friends and family (biological and chosen)."

We have also added text throughout to highlight our methodology. These include the following (added text italicized below):

"However, HIV testing and counseling programmes exist across the U.S., and several new funding initiatives from the Centers for Disease Control and Prevention have encouraged a focus on HIV testing provided specifically to YBMSM populations. By utilising data already being collected in sites such as these, public health programmes can augment existing HIV epidemiology."

"These data demonstrate that even cities with low overall HIV prevalence rates can be settings in which very high HIV incidence rates can exist among vulnerable populations such as young Black MSM*, and that community-based organizations implementing regular HIV testing can contribute valuable incidence information to locally supplement any existing regional or state data."*

3) Did you collect information on HIV testing outside of Project X? If so, how did you handle a participant who reported testing positive somewhere else? Additionally, you state that you confirmed incident cases with the PA DOH but did you also check to confirm your negatives (e.g., check to make sure the participants you called negative were NOT in eHARS)? If you did not assess testing/diagnoses outside of the project, how do you think this would affect your results? Suggest including this in the Discussion.

This is an excellent comment, and speaks to the methodological limitations using this approach. Unfortunately, we were not able to verify negatives. This likely makes our results more conservative, as at least two individuals have reported to us that they eventually went on to test positive at another site, results for whom we could not include in this analysis because we do not have the permissions to access and verify these positive results in eHARS (PA-NEDSS) of someone for whom we did not conduct the positive test. We describe this in the limitations: "First, we were unable through existing data-sharing protocols to identify and include any individuals who tested HIV-negative at our site but who later seroconverted at other HIV testing sites."

Other comments
Page 5, Introduction: provide a reference/source for the estimated HIV prevalence in the city
Page 7,

Thank you for this comment: it is aidsvu, now cited.

Methods: I think that participants had to have 2 HIV tests in order to be included in the cohort, correct? If so, clarify this in the methods.

The reviewer is correct. We have clarified this in the Methods by adding an additional clause (italicized below): "Participants were included in this analysis if they were 13-29 years old at time of first onsite test; identified as male (non-transgender) and Black/African-American; reported sexual activity with males; whose first HIV-antibody test result onsite was negative; *and who received at least two HIV tests onsite*."

Page 7, Results: Suggest providing more information on the population participating in Project X. Do you think they are representative of young MSM in the city? high-risk? lower risk?

We are grateful for this comment. Unfortunately we are not aware of any other published behavioral risk data on other YMSM in this city that we can draw upon that are current. We attempted to address this point by newly presenting and contextualizing site-specific behavioural risk findings among other Black MSM. We direct the reviewer to our response to a previous reviewer (restated here): "At their most recent test, 23 (59.0%)

reported condomless anal intercourse (CAI) with a male partner, and three (7.7%) reported condomless vaginal intercourse with a female. Three individuals (7.7%) reported at most recent test having had sex with an HIV-positive male partner, while 11 (28.2%) reported being unsure whether any male sexual partners were HIV-positive. Twenty-four separate ZIP codes were represented by participants; 96% were from the Pittsburgh region (data not shown)."

We have also added two sentences to the Discussion section that attempt to put the behavioral risks reported by the YBMSM in this sample into context: "While the proportion of YBMSM in this sample reporting condomless anal intercourse (59.0%) appears high, the rate reported here is lower than in other recent studies demonstrating that large majorities of MSM, including those who are Black, engage in CAI.8 Second, sexual behaviour data collected during rapid HIV testing events is streamlined in this region; secondary data analysis offers few opportunities to analyse risk or protective correlates, such as partner number or PrEP/nPEP use. In addition, participants disclose sexual behavior data to test counselors, which may heighten social desirability bias in responses. This suggests that the YBMSM in this sample are not engaging in risky sexual behavior at higher rates than their counterparts in other U.S. locales."

We also added sentences to the limitations section discussing how behavioural data are collected during HIV testing and counseling: "Second, sexual behaviour data collected during rapid HIV testing events is streamlined in this region; secondary data analysis offers few opportunities to analyse risk or protective correlates, such as social determinants, partner number or PrEP/nPEP use. In addition, participants disclose sexual behavior data to test counselors, which may heighten social desirability bias in responses."

Page 7, Results: No need for two decimal places on estimates

We have restricted estimates to one decimal place throughout the text, but have kept two decimal places in Table 1. We defer to the editor here.

Page 8, Results table. It's interesting that the maximum age at both first test and most recent test was 29? Was there no 29 year old who was followed for a year?

Yes—the reviewer is correct. We had one 29-year old who received a total of two tests, but we have no documented HIV testing uptake for this individual after turning 30. Project Silk is funded to serve ages 13-29, but several older people also receive regular HIV testing at the site (including one who seroconverted, but whom we could not include in this analysis due to his age and our interest in restricting the analysis to the CDC-defined YBMSM group).

Page 10, Discussion. This does not "confirm" anything. It does provide additional evidence.

We agree with the reviewer, and have made the change (italicized below): "This analysis *provides additional evidence* that young Black MSM face extraordinarily high risk of HIV acquisition, highlighting that even cities with low prevalence of HIV infection can be settings in which "hidden" epidemics occur among young Black MSM."

Page 11, Key messages: Suggest replacing "confirmation" with "evidence."

We have removed the "Key Messages" section on recommendation from the editors, e.g. it is not appropriate for a Short Report.

How do you know this was "unreported" and "explosive"?

We have removed the "Key Messages" section on recommendation from the editors, e.g. it is not appropriate for a Short Report.