PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Standardized Patient Encounters to Improve Quality of Counseling for Pre-Exposure Prophylaxis (PrEP) in Adolescent Girls and Young Women (AGYW) in Kenya: Study Protocol of a Cluster Randomized Controlled Trial
AUTHORS	Larsen, Anna; Wilson, Kate S.; Kinuthia, John; John-Stewart, G; Richardson, BA; Pintye, Jillian; Abuna, Felix; Lagat, Harison; Owens, Tamara; Kohler, Pamela

VERSION 1 – REVIEW

REVIEWER	Bernadette Hensen London School of Hygiene and Tropical Medicine, London, UK, Faculty of Infectious Diseases
REVIEW RETURNED	11-Dec-2019

GENERAL COMMENTS	Thank you for the opportunity to review this protocol for a trial to evaluate an intervention to address barriers to AGYW uptake and adherence to PrEP. There were some aspects of the intervention and evaluation that were unclear to an outsider, which I've highlighted below. I recommend that the authors revisit the CONSORT CRT checklist to make sure all aspects are covered, as this would make the protocol clearer to readers. It is not clear why the primary outcome of the trial is not uptake and/or adherence amongst AGYW as an outcome? I am sure there is a rationale for this, but it would be useful to include a sentence or two on this in the discussion. Throughout check use of acronyms, at times they're not used despite being defined There is mention of monitoring intervention fidelity, but are there any interviews planned with AGYW who access the services to also assess whether any change seen in the primary outcome by SPs is reflected in in-depth interviews or group discussions with AGYW There needs to be some clarity on the unit of allocation for the intervention, and the unit of analysis; see details of this below under methods. Also, it is not clear whether the SP will be identifiable by the HCWs, and if they are, what implications this has on the findings. Also, how will you determine whether there is consistency in how the SPs assess the quality of PrEP communication between different SPs? Title Need to identify the trial as a cluster randomised trial Abstract Describe how clustering will be taken into account in the analysis The final sentence of the abstract refers to study applicability, is the meaning here generalisability? Introduction

	What age is meant by AGYW? Rephrase the sentence on PrEP effectiveness to efficacy What is meant by PrEP optimisation in the penultimate sentence on Page 4? (line 54) It's not clear in the introduction whether the objectives pertain to the health facility level, the healthcare worker or the SP – this could be made clearer in the introduction but particularly later in the methods (e.g does the intervention pertain to the HCW, and the unit of analysis is the number of visits by SP?) Methods Line 34 page 5 – make clear that this is about the intervention, not study sites and population – there should be a separate heading after Trial design and participants describing the intervention components. One of the criteria for participation of the health facilities is willingness on behalf of the leadership – may be worth considering how this will influence the effectiveness of the intervention and the generalisability of the facilities included. From figure it seems the intervention is applied at facility level and the analysis is at the level of SP visits – this needs to be made more explicit in the text. Health centre is mentioned under randomisation but this wasn't mentioned earlier – how does a health centre differ from a health facility, and would this not be correlated with patient volume? This needs some clarification in the randomisation section. Blinding – are HCWs blinded to who the SP are? Will the SP be identifiable to the HCWs? This detail should be included in the protocol How many repeat trainings will be conducted? I think it would be easier for the reader to understand the intervention if there was a separate sub-heading called Intervention, in line with CONSORT checklist for CRTs. Then one on outcomes and data collection, to clearly delineate the intervention and the evaluation It would be useful to include, on Page 8 line 40-56, how many SPs the study is recruiting, and whether the same SPs will go to all health facilities. This may have implications for consistency in the measure of the study outcome. On page 10 the SPEED trial is mentioned, but no details of this trial are provided. Under intervention evaluation – the SPs conduct repeat visits to the health facilities, is the intention that they are then counselled on adherence to PrEP, as they will already be known as PrEP initiators by the HCW; or will they go to different facilities than the ones they visited at baseline to ask about initiating PrEP? These details aren't clear, also – as mentioned above – it's not clear whether or not the HCW will know who the SP are? Will the HCW know that these are SP? From line 42-43 page 11, it seems that the SP will go to the same health facility they visited at baseline. So they will expect to be counselled on adherence I assume. Is there any risk of contamination? This isn't mentioned. Under sample size page 13 line 48 – it states "given the fixed number of clusters" but it's not clear why there are a fixed number of clusters? This needs to be described. Also, the coefficient of variation of 0.15 is mentioned – but to what level does this pertain? From the sentence after this it seems its SP, but this needs to be clarified. In the analysis, GLMM will be used to estimate the effect at the individual-level, but it's not clear what this means – the level of the HCW or individual SP visits? As SP will be included as a random effect, I assume individual level means HCW – but you only have

	12 HCW per arm, an individual level analysis where there are less than 15 clusters per arm is not recommended. The sample size calculation implies SP, but this needs to made clearer earlier on in the protocol (See CONSORT extension checklist). Ethics and dissemination – please provide details of whether ethical approval has been obtained.

REVIEWER	Dvora Joseph Davey University of California Los Angeles, Epidemiology
REVIEW RETURNED	26-Dec-2019

GENERAL COMMENTS	This is a new study of a cluster randomized trial to evaluate an assessment of clinical training using patient actors in Kenya. The manuscript provides an overview of the study design and protocol. The study design and premise are strong, and needed. Improving HCW competency and communication could have significant impact on PrEP use and adherence in AGYW in Kenya. Below are a few areas that could be considered in an updated manuscript. 1. It is unclear who the HCWs are in the study. Presumably there are multiple levels of HCWs involved including nurses, counselors, lab staff? Would be good to highlight who the actors will interact with and what cadres the intervention will target. Will the training differ by counselor or clinical staff for example? 2. In the introduction the authors mention the need for empathy and reduction in stigma (external stigma presumably), but it is unclear how empathy and stigma will be assess by actors (and addressed in the intervention). The authors mention communication skills but it would be good to have greater detail about stigma and stigma assessments and interventions. 3. Is the mentorship program (in study design) ongoing? How will you differentiate the impact of the mentorship program (unclear what the intervention is) from the future training and SP evaluation? 4. How do you plan on videotaping encounters with the actors? Do the providers know they are being filmed? Seems like there are some ethical and logistical questions here that could be answered. 5. During the training the trainees have a role play session with SPs. Is there a way to ensure that they don't get visited by the same SPs and recognize them? 6. Under outcomes on page 12-13 there is no mention of stigma and empathy again. Are these secondary outcomes? How are they (and change in these indicators) measured? 7. How is PrEP competency (under sample size) defined? What about for different cadres (as asked in point 1 above)? 8. SPs have been used before in Kenya with HCT quality assessment. Can you reference this in the discussion paragraph (line 11-12 on page 16) 9. Limitations- what about different HCW cadre, educational background differences between nurses and counselors and varying roles in PrEP provision?

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Bernadette Hensen
Institution and Country: LSHTM, UK

Overall:

A. There were some aspects of the intervention and evaluation that were unclear to an outsider, which I've highlighted below.

Response A: Thank you for highlighting the aspects that were not clear to outsiders; this has substantially improved the manuscript. We have proposed changes to clarify these areas (more details below).

B. I recommend that the authors revisit the CONSORT CRT checklist to make sure all aspects are covered, as this would make the protocol clearer to readers.

Response B: Thank you for this suggestion. We have addressed the specific items you indicated on pages 8, 9, 11, 12, and 14 of the manuscript (details below), We have reviewed the CONSORT CRT checklist to ensure compliance. We feel all areas are now adequately addressed.

C. It is not clear why the primary outcome of the trial is not uptake and/or adherence amongst AGYW as an outcome? I am sure there is a rationale for this, but it would be useful to include a sentence or two on this in the discussion.

Response C: We agree that it would be useful to clarify why we did not choose PrEP adherence as a primary outcome. We made the decision to use quality of PrEP counseling as the outcome in this trial because other aims of the larger study measure PrEP adherence among AGYW (please see response E, below). As such, we wanted to focus on an important proximate outcome of quality of PrEP services.

We have added a sentence on p.14 to explain, "Quality of PrEP counseling was selected as the primary outcome for this study as it represents an important proximate outcome of improving PrEP services for AGYW that the training intervention may directly influence. PrEP uptake and adherence among AGYW in Western Kenya are evaluated as other important outcomes of programmatic PrEP delivery via separate research activities under the parent grant".

D. Throughout check use of acronyms, at times they're not used despite being defined

Response D: Thank you for highlighting this detail. We have reviewed the use of acronyms in the manuscript and defined the initial instance of use, such as the reference to randomized controlled trials in the introduction which was previously undefined.

E. There is mention of monitoring intervention fidelity, but are there any interviews planned with AGYW who access the services to also assess whether any change seen in the primary outcome by SPs is reflected in in-depth interviews or group discussions with AGYW

Response E: Thank you for this comment. Under the grant supporting this cluster randomized trial, additional activities are undertaken to assess experiences of AGYW seeking PrEP services in Western Kenya. These activities include qualitative in-depth interviews and focus group discussions among AGYW offered PrEP and HCWs delivering PrEP to AGYW to elucidate attitudes, beliefs, and experiences. These qualitative components were conducted prior to the baseline assessment and qualitative findings were used to develop appropriate case scripts and inform didactic training materials for the cRCT intervention. During the end of study evaluation, we plan to include a section in the checklist for the standardized patients to provide open-ended responses.

We describe the role of qualitative findings in informing cRCT activities on p.9 and 12 in the initial submission. To address the reviewer's question, we added a statement describing the section on the SP checklist to capture open-ended responses about the encounter.

p.10, "After the encounter, the SP fills out a post-consultation checklist to assess HCW adherence to national guidelines and communication skills using standardized questions with binary ("done"/"not done") or four-point Likert scale response options. The checklist includes a free-text item eliciting open-ended responses from SPs about each encounter."

F. There needs to be some clarity on the unit of allocation for the intervention, and the unit of analysis; see details of this below under methods.

Response F: Thank you for this observation. We agree this is an important clarification. We have addressed this in detail p.4, p.5, p.14, and p.16 (details below) in response to your specific questions.

G. Also, it is not clear whether the SP will be identifiable by the HCWs, and if they are, what implications this has on the findings.

Response G: Thank you for this important comment. We agree that ensuring SPs are not identifiable by HCW is an important concern. Below we have detailed the study procedures in place to prevent discovery of SPs throughout the trial.

H. Also, how will you determine whether there is consistency in how the SPs assess the quality of PrEP communication between different SPs?

Response H: Thank you for this comment. SPs utilize a standardized checklist to assess the quality of PrEP communication which includes seven items with a four-scale Likert response option.

This is detailed further on p.14, "Seven questions assess communication quality with four scaled response options (strongly agree, agree, disagree, strongly disagree) (sub-score range: 0-21). Because there are few standard tools to assess patient-provider communication about HIV prevention with young people, questions to assess communication quality were informed by guidelines and tools used in other populations and adapted for this population".

The use of a standard checklist is intended to ensure consistency across SPs regarding their assessment of HCW communication skills. SPs are trained in how to approach their responses. Trained study staff administer the checklist to further ensure consistency of data collection across SPs.

We have clarified this process further on p.10 "SPs are trained in how to fill out the checklist and checklists are reviewed by a study team member to ensure completeness and consistency across SPs".

I. Title: Need to identify the trial as a cluster randomised trial

Response I: Thank you for your attention to the title to ensure it is optimally descriptive of the study.

We have added "cluster" to the title on p.1, as "Standardized Patient Encounters to Improve Quality of Counseling for Pre-Exposure Prophylaxis (PrEP) in Adolescent Girls and Young Women (AGYW) in Kenya: Study Protocol of a Cluster Randomized Controlled Trial"

J. Abstract: Describe how clustering will be taken into account in the analysis

Response J: Thank you for this comment. Please find reference to clustering in the abstract on p.2 as, “An intention-to-treat (ITT) analysis will evaluate whether the intervention resulted in higher scores within intervention compared to control facilities, adjusted for baseline SP scores and clustering by facility”

K. The final sentence of the abstract refers to study applicability, is the meaning here generalisability?

Response K: Thank you for this comment, we agree with this word choice and have changed it accordingly on p.3 as, “Study activities are subject to delays from public holidays, provider strikes, PrEP stock-outs, and staff turnover; these challenges depict realities within the health system thus contributing to study generalizability”

Introduction:

1. What age is meant by AGYW?

Response 1: Thank you for this observation. We have added this information on p.4 as “Adolescent girls and young women (AGYW) age 15 to 24 years old in high HIV-burden settings in sub-Saharan Africa (SSA)…”

2. Rephrase the sentence on PrEP effectiveness to efficacy

Response 2: Thank you for this comment. We have updated this on p.4 as, “Pre-exposure prophylaxis (PrEP) has been shown to be highly efficacious to prevent HIV transmission among adults…”

3. What is meant by PrEP optimisation in the penultimate sentence on Page 4?

Response 3: Thank you for this comment. We have addressed this phrasing on p.4 as, “Results from this study could demonstrate an evidence-based, scalable intervention to improve delivery of PrEP as an attractive HIV prevention option…”

4. (line 54) It’s not clear in the introduction whether the objectives pertain to the health facility level, the healthcare worker or the SP – this could be made clearer in the introduction but particularly later in the methods (e.g does the intervention pertain to the HCW, and the unit of analysis is the number of visits by SP?)

Response 4: Thank you for this important observation. We have made multiple revisions to improve clarity.

Introduction, p.4, “This cluster randomized controlled trial (cRCT) will evaluate impact of a SP training intervention on the quality of PrEP counseling at the visit-level, including communication skills and adherence to national guidelines[30], provided by HCWs delivering PrEP to AGYW”.

Methods, p.5, “This cluster-RCT compares HCW adherence to national PrEP delivery guidelines and communication skills between the intervention and comparison facilities assessed post SP-led training intervention. PrEP delivery by HCW is evaluated via standardized checklists prepared by SPs acting as “mystery shoppers” during unannounced PrEP-seeking encounters. PrEP delivery scores are measured at the SP encounter level and compared between intervention and control sites, clustering by facility.”

We have also addressed this comment further in the “Methods” section per your questions below.

Methods:

5. Line 34 page 5 – make clear that this is about the intervention, not study sites and population – there should be a separate heading after Trial design and participants describing the intervention components.

Response 5: Thank you for this comment, we agree that the section “Standardized patient actor selection and training” is more appropriately located in the, “Study procedures” section on p.8. As such, we moved the entire “Standardized patient actor selection and training” section to p.8.

6. One of the criteria for participation of the health facilities is willingness on behalf of the leadership – may be worth considering how this will influence the effectiveness of the intervention and the generalisability of the facilities included.

Response 6: Thank you for this comment. We agree that the prior wording of this sentence made it seem that some facility managers were unwilling for their facilities to be involved in the study. In theory, facilities that are unwilling to allow our study to be conducted there may differ from facilities that do, in terms of population or services. We maintain strong working relations with county officials and facility managers. In our experience, most facility managers are very receptive to our research and program implementation, especially when it involves staff training in HIV services. In this study, zero of 24 facility managers approached refused to participate. Thus, we feel the findings from our study generalize to facilities serving AGYW with HIV prevention services in Western Kenya. In response to this question, we revised the sentence on page 6 to include a statement about the number of facilities that refused. In the discussion, we added a statement on page 6 about the generalizability.

p.6, “Thirty-seven facilities were evaluated for inclusion, of which 24 were purposively selected based on expected patient volume of at least two AGYW seeking PrEP per week.All facility managers approached for inclusion agreed to participate in the study.”

p.6, “Sampling aimed for an even distribution across facility levels (county, sub-county, health center), settings (urban, peri-urban, rural), and types (public, private/faith-based) to ensure generalizability of results.”

7. From figure it seems the intervention is applied at facility level and the analysis is at the level of SP visits – this needs to be made more explicit in the text.

Response 7: Thank you for this comment. We agree that this is an important clarification and have revised the manuscript to clarify in multiple locations:

p.4, “This cluster randomized controlled trial (cRCT) will evaluate impact of a SP training intervention on the quality of PrEP counseling at the visit-level, including communication skills and adherence to national guidelines[30], provided by HCWs delivering PrEP to AGYW.”

p.5, “This cluster-RCT compares HCW adherence to national PrEP delivery guidelines and communication skills between the intervention and comparison facilities assessed post SP-led training intervention. PrEP delivery by HCW is evaluated via standardized checklists prepared by SPs acting as “mystery shoppers” during unannounced PrEP-seeking encounters. PrEP delivery scores are measured at the SP encounter level and compared between intervention and control sites, clustering by facility.”

p.14, “The primary outcome of interest for this study is quality of PrEP counseling provided by HCWs delivering PrEP to adolescent girls and young women for HIV prevention in Kenya, measured at each unique SP encounter and compared between intervention and control sites.”

p.16, “The primary analyses will use intention-to-treat (ITT) to evaluate whether the clinical training intervention using SPs results in higher quality of PrEP counseling scores at SP encounters taking place in intervention facilities compared to control facilities.”

p.16, “Generalized linear mixed models (GLMMs) will be used to compare post-intervention quality of PrEP counseling score percent from SP encounters between the intervention facilities and comparison facilities. (i.e., control arm)”

p.16, “We will estimate the effect of the training intervention on the individual SP encounter level, using a GLMM with a Gaussian distribution and identity link, accounting for facility cluster and SP as random effects.”

p.16, “This analytical approach allows individual-level outcomes per SP encounter to be modeled while accounting for correlation by cluster and SP.”

8. Health centre is mentioned under randomisation but this wasn’t mentioned earlier – how does a health centre differ from a health facility, and would this not be correlated with patient volume? This needs some clarification in the randomisation section.

Response 8: Thank you for this helpful comment. Throughout the manuscript, we use the term “facility” to refer to any health facility regardless of level. In the description of the randomization process, we distinguish between facility level, specifying that facilities either fall into the category of “county or sub-county hospital” or “health center”. These are common terms used within the Kenyan national health system.

We have clarified this with revision to this sentence on p.7, “Facility cluster randomization is conducted using a stratified approach based on facility level (county/sub-county hospital vs. health center)”.

We have also clarified that patient volume is specifically “patient volume of PrEP clients”, not overall facility patient volume, p.7 “facility patient volume of PrEP clients (≥5 female PrEP clients per week [high volume] vs. <5 female PrEP clients per week [low volume])”.

Facility level and patient volume of PrEP clients are not highly correlated, as some county/sub-county hospitals have low patient volume of PrEP clients and some health centers have high patient volume of PrEP clients, as indicated by the distribution presented in Table 1.

We have addressed this concern on p.7 as, “Stratification groups were selected to further reduce potential imbalance between intervention and control facilities. We do not expect that facility level and volume of AGYW seeking PrEP would be meaningfully correlated because facility-level patient volume of PrEP clients is not determined by facility level within the health system in Western Kenya.”

9. Blinding – are HCWs blinded to who the SP are? Will the SP be identifiable to the HCWs? This detail should be included in the protocol

Response 9: Thank you for this comment. We agree it is important for the identity of SPs to remain hidden. To improve clarity about the SPs and their identifiability by HCWs, we have added the following sentences.

To the blinding section on p. 8, “In their roles as “mystery shoppers”, unannounced SPs are trained to be indistinguishable by HCW from real AGYW seeking services within study sites, thus HCW are in essence “blinded” to SPs. During the classroom role-play encounters within the clinical training intervention, SPs are known to the HCW as actresses. To reduce discovery of unannounced SPs in the post-intervention evaluation, different actresses from those participating in the baseline assessment and training intervention are employed as “mystery shoppers”.

Other procedures to ensure unannounced SPs are hidden to HCWs are detailed elsewhere in the manuscript (further details below in response to other questions).

10. How many repeat trainings will be conducted? I think it would be easier for the reader to understand the intervention if there was a separate sub-heading called Intervention, in line with CONSORT checklist for CRTs. Then one on outcomes and data collection, to clearly delineate the intervention and the evaluation It would be useful to include, on Page 8 line 40-56, how many SPs the study is recruiting, and whether the same SPs will go to all health facilities. This may have implications for consistency in the measure of the study outcome.

Response 10: Thank you for these comments. We have moved and retitled the former sub-category “Intervention approach using standardized patients” to now serve as its own category titled “Intervention”.

We have reorganized the intervention section to improve clarity and have specified the number of repeat trainings on p.11 as, “Enrolled HCWs from the 12 study sites randomized to receive the clinical training intervention are invited to attend two-day training events among groups of 5-10 HCWs, totaling 20 repeated training events”.

We have clarified the number of SPs and their deployment to health facilities on p.8-9 as, “Two SPs are assigned to each case script for a total of eight SPs who consistently perform cases at all health facilities throughout the baseline assessment and clinical training intervention. After the intervention period, a new group of SPs are hired and trained to perform unannounced case scripts in the same manner for the post-intervention evaluation to reduce chance of SP discovery by HCWs.”

Further, we have renamed sub-sections to indicate data collection steps on p.9 as “Baseline data collection through surveys and unannounced patient actor encounters” and on p.12 as “Data collection for intervention evaluation”.

“Outcome measures” was a pre-existing category in the original version on p.14, thus we feel this is adequately labeled per CONSORT guidelines.

11. On page 10 the SPEED trial is mentioned, but no details of this trial are provided.

Response 11: Thank you for this comment. We have provided details of the SPEED trial and highlighted the publication provided which provides interested readers with further information.

p.12, “The clinical training intervention is adapted from the training intervention implemented in the SPEED trial – a stepped-wedge RCT evaluating the effect of a SP-led training intervention on adolescent retention in HIV care in Kenya (details published previously)[24].”

12. Under intervention evaluation – the SPs conduct repeat visits to the health facilities, is the intention that they are then counselled on adherence to PrEP, as they will already be known as PrEP initiators by the HCW; or will they go to different facilities than the ones they visited at baseline to ask

about initiating PrEP? These details aren't clear, also – as mentioned above – it's not clear whether or not the HCW will know who the SP are? Will the HCW know that these are SP? From line 42-43 page 11, it seems that the SP will go to the same health facility they visited at baseline. So they will expect to be counselled on adherence I assume.

Response 12: Thank you for these helpful requests for clarity. We have clarified that the SPs performing the intervention evaluation are different SPs than those who performed case scripts during baseline unannounced visits and the training intervention in multiple places.

p.13, "The new group of SPs are hired and trained to perform case scripts and, subsequently, SPs repeat the unannounced assessments conducted during the baseline evaluation at all 24 intervention and control sites. Case scripts are updated from those used at baseline and in the training intervention to minimize risk of SP discovery by HCWs."

The use of new SPs for the intervention evaluation was previously described on p.8, "To reduce discovery of unannounced SPs in the post-intervention evaluation, different actresses from those participating in the baseline assessment and training intervention are employed as "mystery shoppers"."

p.9 "After the intervention period, a new group of SPs are hired and trained to perform unannounced case scripts in the same manner for the post-intervention evaluation to reduce chance of SP discovery by HCWs."

We previously clarified that the SPs are not known to the HCWs on p.8, "In their roles as "mystery shoppers", unannounced SPs are trained to be indistinguishable by HCW from real AGYW seeking services within study sites, thus HCW are in essence "blinded" to SPs. During the classroom role-play encounters within the clinical training intervention, SPs are known to the HCW as actresses. To reduce discovery of unannounced SPs in the post-intervention evaluation, different actresses from those participating in the baseline assessment and training intervention are employed as "mystery shoppers".

13. Is there any risk of contamination? This isn't mentioned.

Response 13: Thank you for this comment. We have clarified the low risk of contamination on p.7 as, "We do not expect contamination between intervention and control sites, as selected facilities are geographically located with sufficient distance from each other to limit HCW interaction between facilities."

14. Under sample size page 13 line 48 – it states "given the fixed number of clusters" but it's not clear why there are a fixed number of clusters? This needs to be described. Also, the coefficient of variation of 0.15 is mentioned – but to what level does this pertain? From the sentence after this it seems its SP, but this needs to be clarified.

Response 14: We agree that we could clarify our sample size assumptions, We have reworded this to clarify on p.15, "Given the study is conducted in 24 facilities comprising the total number of clusters…".

We have further clarified the coefficient of variation on p.15, "…and assumed coefficient of variation between SP encounters of 0.15"

15. In the analysis, GLMM will be used to estimate the effect at the individual-level, but it's not clear what this means – the level of the HCW or individual SP visits? As SP will be included as a random effect, I assume individual level means HCW – but you only have 12 HCW per arm, an individual level

analysis where there are less than 15 clusters per arm is not recommended. The sample size calculation implies SP, but this needs to made clearer earlier on in the protocol (See CONSORT extension checklist).

Response 15: Thank you for your comment. We have clarified this earlier in the manuscript, per your prior suggestion (See response to #4).

We have further clarified on p.16, “We will estimate the effect of the training intervention on the individual SP encounter level” and “This analytical approach allows individual-level outcomes per SP encounter to be modeled while accounting for correlation by facility-level cluster and SP”

16. Ethics and dissemination – please provide details of whether ethical approval has been obtained.

Response 16: Thank you for this important suggestion. We have clarified that ethical approval has been obtained by US- and Kenyan-based institutions on p.16, “The PrIYA-SP study is registered at clinicaltrials.gov. This study was approved by the University of Washington Institutional Review Board (IRB) and Kenyatta National Hospital Ethics and Research Committee (ERC). Changes to the protocol are reviewed by both institutions prior to implementation and appropriate updates are made to clinicaltrials.gov.”

Reviewer: 2
Reviewer Name: Dvora Joseph Davey
Institution and Country: UCLA, USA

1. It is unclear who the HCWs are in the study. Presumably there are multiple levels of HCWs involved including nurses, counselors, lab staff? Would be good to highlight who the actors will interact with and what cadres the intervention will target. Will the training differ by counselor or clinical staff for example?

Response 1: Thank you for this helpful observation. We agree that it is important for readers to understand the cadres included in this study.

We have clarified the common cadres trained to deliver PrEP in Kenya on p.6, “Within Kenyan FP and MCH settings, nurses, clinical officers, and doctors predominantly comprise the HCW cadres trained to deliver PrEP, with other cadres such as HIV Testing Services counsellors less frequently involved.”

We have also added the following sentence to p.11 under “Intervention”, “All HCWs, regardless of cadre, will receive the same two-day training to ensure consistency of exposure to PrEP delivery guidelines and patient-provider communication content.”

Further, we added the following sentence to p.11, “Overall, the clinical training intervention is developed to accommodate a mixed skillset within diverse HCW cadres that could be applied and sustained across the health system by the Kenyan Ministry of Health.”

2. In the introduction the authors mention the need for empathy and reduction in stigma (external stigma presumably), but it is unclear how empathy and stigma will be assess by actors (and addressed in the intervention). The authors mention communication skills but it would be good to have greater detail about stigma and stigma assessments and interventions.

Response 2: Thank you for this comment. We agree that the use of the word “empathy” in this instance in the introduction is unnecessary to include here since we do not explain this complex term

further in the introduction. We have removed this reference, such that the sentence in the introduction now reads (p.4): “SPs are especially effective at improving and assessing HCW skills in patient-centered communication, a key component of quality of care[29], and adherence to clinical guidelines[24].”

Empathy is discussed within the didactic sessions of the training intervention and is measured as a construct in the interpersonal skills assessment within the SP training checklist. We agree that this was not previously explained, thus we have added a sentence on page 11 about empathy in the didactic session, and on page 15 about assessing empathy:

p.11, “Interactive group activities include a values clarification exercise and patient-centered communication activity which focuses on understanding the patient’s perspective, verbal and nonverbal communication, expressing empathy, and shared decision-making.”

p.15, “Empathy is assessed indirectly as a construct within the interpersonal skills assessment, measured as a combination of skills including active listening and validation.”

We agree with the reviewer that that stigma is not measured in this study and the clinical training does not directly intervene on stigma. In response to this question, we reviewed the manuscript for mention of stigma and did not find one. As such, we did not see the need to make further changes to the manuscript based on this question.

3. Is the mentorship program (in study design) ongoing? How will you differentiate the impact of the mentorship program (unclear what the intervention is) from the future training and SP evaluation?

Response 3: Thank you for this helpful observation. We have clarified that the mentorship program is no longer ongoing on p.5, “PrIYA was followed by a PrEP mentorship program in 21 additional sites involving in-clinic guidance from former PrIYA nurses to HCW in non-PrIYA sites about best practices for delivering PrEP to AGYW. Following conclusion of the PrEP mentorship program, we initiated the present follow-on study in 24 former PrIYA and PrEP mentorship sites.”

The “Statistical methods and analysis” section clarifies that the intention-to-treat analysis comparing quality of PrEP counseling scores between intervention and control sites will be adjusted for baseline PrEP counseling scores, thus adjusting for variability in quality of PrEP delivery prior to the training that may be based on prior programs (e.g., PrIYA or the PrEP mentorship program).

p.16, “These models will be adjusted for baseline quality of PrEP counseling score items that differ between study arms (p-value <0.05) ascertained using checklists completed by SP actors based on their assessment of care received by HCWs during unannounced SP encounters”

4. How do you plan on videotaping encounters with the actors? Do the providers know they are being filmed? Seems like there are some ethical and logistical questions here that could be answered.

Response 4: Thank you for this comment. We have clarified this on p.12, “During the informed consent process, HCW agree to video recording during the training sessions; video equipment is readily visible in role-play spaces such that HCW are aware of the recording. HCW may opt to sign a video and photo release form premising use of the videos in educational or dissemination settings beyond the training event.”

5. During the training the trainees have a role play session with SPs. Is there a way to ensure that they don’t get visited by the same SPs and recognize them?

Response 5: Thank you for these helpful requests for clarity. We have clarified that the SPs performing the intervention evaluation are different SPs than those who performed case scripts during baseline unannounced visits and the training intervention in multiple places.

p.13, “The new group of SPs are hired and trained to perform case scripts and, subsequently, SPs repeat the unannounced assessments conducted during the baseline evaluation at all 24 intervention and control sites. Case scripts are updated from those used at baseline and in the training intervention to minimize risk of SP discovery by HCWs.”

The use of new SPs for the intervention evaluation was previously described on p.8, “To reduce discovery of unannounced SPs in the post-intervention evaluation, different actresses from those participating in the baseline assessment and training intervention are employed as “mystery shoppers”.”

p.9 “After the intervention period, a new group of SPs are hired and trained to perform unannounced case scripts in the same manner for the post-intervention evaluation to reduce chance of SP discovery by HCWs.”

We previously clarified that the SPs are not known to the HCWs on p.8, “In their roles as “mystery shoppers”, unannounced SPs are trained to be indistinguishable by HCW from real AGYW seeking services within study sites, thus HCW are in essence “blinded” to SPs. During the classroom role-play encounters within the clinical training intervention, SPs are known to the HCW as actresses. To reduce discovery of unannounced SPs in the post-intervention evaluation, different actresses from those participating in the baseline assessment and training intervention are employed as “mystery shoppers”.

6. Under outcomes on page 12-13 there is no mention of stigma and empathy again. Are these secondary outcomes? How are they (and change in these indicators) measured?

Response 6: Thank you for this comment. We have removed the use of the word “empathy” in the introduction. Please refer to Response 2 regarding stigma.

7. How is PrEP competency (under sample size) defined? What about for different cadres (as asked in point 1 above)?

Response 7: Thank you for this comment. We agree that the use of the word “competency” was confusing, as elsewhere we described this outcome as “quality of PrEP counseling”. We changed the wording throughout to ensure consistent use of the primary outcome of “quality of PrEP counseling”.

8. SPs have been used before in Kenya with HCT quality assessment. Can you reference this in the discussion paragraph (line 11-12 on page 16)

Response 8: Thank you for this comment. We agree with adding references to prior studies/programs using SPs in Kenya. We have cited Wilson et al. work with SPs in Kenya regarding adolescent-friendly HIV services. We also added a citation to Daniels et al. work using SPs to assess quality of healthcare in Kenya (p.4). Further, we added a citation to Wafula et al. work using SPs to assess quality of medicines within Kenyan health facilities (p.4).

9. Limitations- what about different HCW cadre, educational background differences between nurses and counselors and varying roles in PrEP provision?

Response 9: Thank you for this comment. As stated in the response to #1, HCW delivering PrEP to AGYW in FP and MCH settings are predominantly nurses, clinical officers, and doctors. Specifically for their roles in PrEP delivery, these cadres receive the same training in the same skillsets and serve the same daily functions for PrEP delivery based on the Kenyan National PrEP delivery guidelines. Therefore, we do not feel there is meaningful variability in HCW roles in PrEP provision that this serves as a limitation. However, as variation in cadre is a component of real-world PrEP implementation, we developed a training to accommodate a mixed skillset that could be applied and sustained by the Kenyan Ministry of Health.

We have added a sentence to describe this, p.12, “Overall, the clinical training intervention is developed to accommodate a mixed skillset within diverse HCW cadres that could be applied and sustained across the health system by the Kenyan Ministry of Health.”

VERSION 2 – REVIEW

REVIEWER	Dvora Joseph Davey University of California Los Angeles, Epidemiology
REVIEW RETURNED	10-Feb-2020

GENERAL COMMENTS	Great revision of the manuscript.