PROTOCOL COVER PAGE

Protocol Title	Standardized Patients to Measure and Address Intersectional Stigma: An HIV Prevention Engagement Strategy
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Scientific Assessment	Nationally based, federal funding organization.
Version Number/Date:	Version 0.2, 11/2/2021

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1.2	9/19/2019	Response to stipulations following IRB from 9/13/2019. Clarifications regarding provider consent for case script field testing, contact information for study team, details on terms of study termination, details of clinic visits, and procedures for informing SPs of what to expect as part of the job.	Yes
1.3	11/04/2019	Adopted alternative approach to recruitment and maintenance of CABs based on local input.	Yes
1.4	12/1/2020	Amended clinic recruitment procedures (12.1) to reflect the assistance we are now receiving from the Guangzhou CDC and to record the actual number of clinics in our sample pool (46 instead of 81)	Yes
1.5	1/5/2021	Amended the consent procedures (22.1 and 22.3 sections): Waiver of written consent	Yes
1.6	1/12/2021	Added a new qualitative research component: Aiming to study how the SPs' background, sexual identity and LGBT community experience play a role in their study engagement and potentially change after the participation, by conducting interviews before and after their clinic visits: Study endpoints (3.2): Inserted the description of the endpoints/findings we expect from this qualitative interview Procedures involved (5.2): Illustrated the main change on the study procedures in the preparatory stage Consent process (22.1): Illustrated the add-on consenting process for this particular purpose	Yes

1.7	2/17/2021	Added a clause in consent procedures pertaining to qualitative sub-study indicating that participation is voluntary and will not impact their work as an SP.	Yes
1.8	5/27/2021	The measurement tools (SP scripts and healthcare checklist) were revised to reflect the suggestions provided by the recruited SPs and volunteer clinicians during the training. The changes were notified to the SP members (p13).	No
2.0	7/29/2021	Updated the version 1 protocol to include new descriptions of the phase 2 research which includes the RCT related activities such as the intervention design and implementation, as well as collection of follow-up data.	No
2.1	11/02/2021	Update the payment details for participants, clarified logistics for the qualitative interviews. Consent forms revised to remove any language pertaining to arm, as well as to include information about the hybrid training design and participant compensation.	Yes
2.2	09/01/2022	Update the data banking plan in section 6	Yes

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ABBREVIATIONS/DEFINITIONS

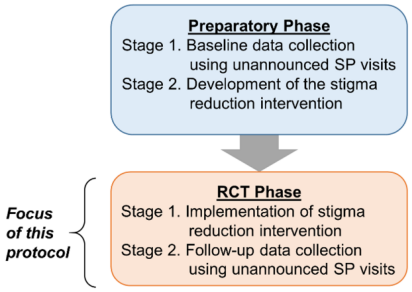
CAB	Community advisory board
EOC	Erosion of care
MSM	Men who have sex with men
GDCDC	Guangdong Center for STD Control and Prevention
PLWH	People living with HIV/AIDS
RCT	Randomized control trial
RERI	Relative excess risk due to interaction
ROR	Return of results
SMC	Safety monitoring committee
SP	Standardized patient
STD	Sexually transmitted disease

1.0 Objectives

1.1 *Purpose*

This is the second phase of a two-phase study that aims to develop and evaluate an intervention to reduce enacted stigma in healthcare settings aimed at PLWH and MSM in China. The **1) preparatory phase** consists of collecting baseline data and conducting formative research in order to inform design of the **2) RCT phase** of research. Although funding for both the preparatory and RCT phases have been secured, we developed study protocols for each phase in an iterative fashion to ensure the opportunity to properly incorporate results from the preparatory phase into the final design of the RCT. The overall scheme of the two study phases are illustrated in Figure 1 below.

Figure 1. Schemata for overall study design.



Having completed all preparatory phase activities, this protocol will describe activities related to the **RCT phase** which will be conducted in two stages:

Stage 1 of the RCT Phase: Implementation of the stigma reduction intervention. A three-module provider training course designed during the preparatory phase will be administered to consenting providers employed at clinics randomized to the treatment arm of the study. The first module will be administered as a one-day training on site at the Guangdong Center for STD Control and Prevention. This will be followed by two online modules that provider participants will complete on their own. Design of this intervention has been informed by results of the baseline study and incorporates expert input from members of our community advisory boards (CAB), one made up of community members and the other of providers. Content of the intervention will include knowledge and skills training on topics including clinical management of common STIs, shared decision making, sexual history taking, and working with non-traditional/marginalized populations. Training methods for the onsite training will include didactic lectures, group-based discussion, and medical simulation and feedback with trained SPs. Methods for the online follow-up sessions will include webinars, short training videos, and multiple choice quizzes.

Stage 2 of the RCT Phase: Follow-up data collection. Follow-up collection using the same unannounced SP visit approach as in the baseline data collection will take place within 1-3 months of the end of the stigma reduction intervention. Briefly, this will consist of working with trained actors who are recruited from the community, who receive training to conduct unannounced clinic visits with consenting providers for the purposes of observing their clinical performance. SPs

will present clinically standardized case scenarios, but the HIV status and sexual orientation of each case will be randomly varied in order to quantify the extent to which HIV stigma and/or homophobia potentially contribute to the deterioration of care quality. Enrolled providers already provided their consent for both rounds of unannounced clinic visit during the preparatory phase of research.

Research activities in all phases of the project will take place in Guangzhou, China.

2.0 Background

2.1 *Significance of Research Question/Purpose*

Consistent data highlight the central role of stigma in limiting uptake of HIV related testing, treatment, and care.[1–3] This is particularly true for gay, bisexual, and other MSM who have the lowest rates of engagement with the healthcare system[4,5] despite bearing the highest HIV incidence burden.[6] Particularly for MSM seeking HIV testing services, enacted stigma—acts of discrimination or hostility directed at a person because of their perceived stigmatized status[7]—both on account of their same-sex behaviors[8] (i.e. sexuality stigma[9] or homophobia) and the perception of their elevated HIV risk[10] (HIV stigma) is all too common.

A major challenge to date in reducing healthcare stigma is our limited ability to measure it.[11] Numerous interventions for providers, for example, have assessed program impact by comparing participants' self-reported attitudes towards PLWH before versus after the intervention, a measure fraught with social desirability bias. Documentation of patient experiences in clinical settings, though less subject to social desirability, may suffer recall bias and also lack standardization across patients. Inability to observe the very behaviors they seek to change also limits the design of these interventions from using insights beyond theoretical reasoning to specify the underlying causes and solutions of stigma.[2,12,13]

By contrast our experimental SP audit method provides a window of insight into provider behaviors *as they unfold in real clinical settings*, providing an objective and standardized measure of stigma amenable to comparison across studies and settings. Our SPs will be recruited from among MSM living locally, whose group makeup will be managed to reflect the overall characteristics of the local MSM community in terms of age, ethnicity, and socioeconomic status. SPs will be trained to consistently present a standardized case to providers. Using an experimental audit design, we will randomly vary the HIV infection status and sexual orientation of all of our SPs. Stigma will be evaluated by comparing the quality of care that SPs experience during provider visits. Quality of care will be measured by administration of a standard of healthcare checklist to SPs following each visit, and which will include items related to provider behaviors including the types of questions asked, accuracy of the preliminary diagnosis, body language and bedside manner (checklist included in Appendix 1). Differences in tallied aggregate scores across SP visit scenarios (e.g. HIV positive versus HIV negative presentations) will be quantified as the enacted healthcare stigma attributable to the condition in question (i.e. HIV infection). In addition, SPs will participate in post-visit "debrief sessions" with another member of the study staff immediately following each visit to recount any other possible features of the visits—both positive and negative—not accounted for in the healthcare quality checklist. This method of quantifying stigma will not be used to identify individual providers or

instances of poor treatment but rather to characterize population level incidence and patterns of stigma enacted by providers towards vulnerable patients. Lastly, the impact of the intervention on overall HIV testing volumes in study facilities will also be evaluated by examining aggregate counts of facility-level HIV tests conducted during the baseline and follow-up observation periods. This information will be provided by the laboratory departments of all participating facilities. This technique of data collection has been successfully piloted with a clinic-based intervention administered by the GDCDC.

In the final step of the initial preparatory phase of this project, we conducted a preliminary and descriptive analysis of the SP-collected baseline clinic visits in order to characterize the nature and patterns of enacted healthcare stigma towards PLWH and MSM. Results quantified the amount of HIV and sexual stigma observed in study clinics (further details of the outcome in Section 3.0), and also stratified results by broadly descriptive characteristics such as age, sex, and rank of provider. These results were shared in Return of Results (RoR) sessions with members of community advisory boards (CABs), one made up of MSM and the other of providers through separate share back sessions. We convened meetings with CAB members to solicit their insights about drivers of provider behaviors observed in their community. The team incorporated CAB feedback to develop the intervention, a stigma reduction training program for provider participants employed at clinics randomized to the treatment arm. Details of the final design were informed by feedback from study team members and each of the two CABs, the overall structure consists of didactic content as well as experiential learning using simulation-and-feedback sessions with trained SPs. We may re-consult our CABs at later stages of the design for iterative feedback on any adjustments made to the intervention design.

In the RCT phase of this project, covered by the current protocol, we will administer the intervention to all consented and enrolled providers employed at study clinics randomized to the treatment arm. We will also conduct a second round of unannounced SP clinic visits to collect follow-up data in order to estimate the impact of the intervention on provider behaviors. The intervention design is largely informed by the Information-Motivation-Behavioral Skills model of behavior change as well as by input from the two CABs during the return of result sessions. The finalized version of the intervention is expected to take a hybrid form consisting of both in-person, onsite sessions and self-directed online sessions for participants to complete in their own time within a specified window of time. Within 1-3 months following the stigma reduction intervention, unannounced SP clinic visits will recommence using the same procedures and data collection techniques as for the baseline visits. Data from the healthcare quality checklists will be integrated into a score for each visit and used to estimate the impact of the stigma reduction intervention. Facility level information on HIV testing will also be collected in the form of aggregate counts as a secondary outcome in order to compare testing volume in the baseline versus follow-up observation periods.

2.2 *Preliminary Data:*

Members of our research team have made key contributions to the field's understanding of the Chinese HIV epidemic, prevention seeking barriers among MSM, and the role of stigma plays in both phenomena. Co-PI Dr. Sean Sylvia and project consultant Dr. Li Li have both successful implemented use of unannounced SP approaches for evaluation of healthcare quality,[14–17] including one application to

assess HIV stigma in China.[18] These projects demonstrate the feasibility of our approach and provide our team with a wealth of knowledge on best practices. Dr. Li's extensive research on HIV-related stigma in Chinese healthcare settings[19–22] underlies the central justifications of this proposal and driving the central hypothesis that its remedy will lower HIV testing barriers for marginalized communities.

In preparation for the current study, the research team previously conducted preliminary pilot activities from September 2018 to January 2019 in Guangzhou, China. We enlisted local stakeholders (MSM, PLWHA, and STD providers) to provide input on preliminary study materials such as disease case scripts, recruited and trained 4 SPs, and conducted 17 total visits with 10 local consenting STD clinics. Though the sample size is too small to draw population level conclusions, instances of both positive and negative interactions with providers were documented by our SPs. The pilot study also allowed the team to resolve logistical challenges (e.g. consent procedures, number of clinic visits to be conducted in a day) and to monitor for potential adverse events, of which none were reported.

2.3 *Existing Literature:*

Limitations to measuring of Stigma Experienced in Healthcare Settings: Existing studies have documented how stigma towards PLWH and marginalized groups including sexual minorities impede access to the HIV prevention continuum at multiple points. An extensive body of literature documenting past stigma reduction interventions suggests that these efforts have had moderate to mixed success.[12,23,24] Yet common across the literature is the collective uncertainty about the state of the science given issues with existing approaches to measurement of stigma.[11] Nearly all studies rely on the self-reported attitudes and beliefs among providers regarding PLWH or other associated groups, an approach fraught with recall and social desirability bias.[25,26] Alternative approaches include direct observation of provider behaviors or monitoring of the patient population for reporting of adverse provider interactions. But both approaches face their own limitations, as providers have known tendencies to alter behaviors under observation (the Hawthorne effect); whereas the lack of standardization across patient-reported events makes it difficult to draw firm conclusions about discriminatory treatment.

Standardized Patients to Measure Care Quality: A key feature of medical training in many settings,[27,28] SPs are an increasingly common tool for researching healthcare quality.[14,15,29,30] Their ability to objectively document provider behaviors through unannounced visits to practices presents a simple solution to the longstanding challenges of stigma measurement such as low provider willingness to self-report discriminatory behaviors or the Hawthorne effect.[13,31] Studies have used unannounced visits from SPs to evaluate the quality of care received by patients in the US[32] and several low and middle-income countries[30] including China.[14–17]

Experimental Audits: Our use of the unannounced SPs in an experimental audit approach (common in social science studies of race and sex discrimination[33–35]) by randomly varying the sexual orientation and HIV status of each SP case scenario. Measuring stigma as both a healthcare quality index score and through documentation of adverse clinical encounters (e.g. care refusal, discriminatory language) provides quantitative and qualitative measures of sexual, HIV, and intersectional stigma.

2.4 *Research Team*

This research will be carried out under the auspices of a multi-PI structure, co-led by co-PI's Dr. Kumi Smith of the University of Minnesota Twin Cities and Dr. Sean Sylvia of the University of North Carolina Chapel Hill.

Administration: Both PIs (Drs. Smith and Sylvia) will provide oversight of the entire program and development and implementation of all policies, procedures and processes. In these roles, they will be responsible for the implementation of the scientific agenda and ensure that systems are in place to guarantee institutional compliance with US and Chinese laws as well as DHHS and NIH policies, including protection of human subjects

PI#1 Dr. Smith will serve as contact PI and will assume fiscal and administrative management for this project. She will be responsible for communication with NIH and submission of annual reports. She will also be responsible for implementation of all human subject research approvals at the University of Minnesota and Guangdong Center for STD Control and Prevention in China.

PI#2 Dr. Sylvia will be responsible for development and adherence to the study protocol and will maintain routine communication with local study staff to monitor for any adverse events related to the study. He will also be responsible for implementation of all human subject research approvals at the University of North Carolina.

Communication and coordination: The PIs will be responsible for overall conduct of the study. During the initial study period, the PIs will conduct weekly meetings with all the co-investigators to discuss study design and research implementation. Subsequently, weekly meetings will be held either by phone, email, Skype conference, or in person for the discussion of project operations and other activities. Throughout the study implementation period the PIs will conduct weekly calls will local study staff and co-I's based at the study site in Guangzhou to ensure adherence to the study timeline, maintain protocol standards, and to address any issues that may arise. The two PIs will develop a comprehensive data analysis plan to be presented to all co-investigators prior to start of analyses. The PIs will work together to discuss any changes in the direction of the research projects. A publication policy will be established based on the relative scientific contributions of the PIs and key personnel. Dr. Smith will serve as the contact PI and be responsible for submission of progress reports to NIH and all communication.

Conflict Resolution: If a potential conflict develops, the PIs shall meet and attempt to resolve the dispute. The PIs have worked successfully together for the past several years and there is very low probability that differences of opinion cannot be managed effectively between them. If they fail to resolve the dispute, the disagreement will be referred to an arbitration committee consisting of two impartial senior executives from the University of Minnesota and the University of North Carolina and a third impartial senior executive mutually agreed upon by both PIs. No members of the arbitration committee will be directly involved in the research grant or disagreement.

Change in PI Location: If a PI moves to a new institution, attempts will be made to transfer the relevant portion of the grant to the new institution. In the event that a PI cannot carry out his/her duties, a new PI will be recruited as a replacement at one of the participating institutions.

3.0 Study Endpoints/Events/Outcomes

3.1 *Primary Endpoint/Event/Outcome*

Our primary endpoint of the RCT phase of the study will be the quality of healthcare received by SPs in each clinical encounter with an enrolled provider. As a measure of the quality of healthcare provided in each interaction between physicians and standardized patients, we will create an index using 38 items from the structured post-interaction survey questionnaire administered to SPs following each unannounced visit. Individual items will be combined into a global index, $\overline{s_i}$, which is calculated as a weighted average of all 38 items, for which weights are calculated as the sum of its row entries in the inverted covariance matrix as follows:

$$\overline{s_i} = \left(1'\hat{\Sigma}^{-1}1\right)^{-1}\left(1'\hat{\Sigma}^{-1}y_i\right)$$

where 1 is a column vector of 1s, $\hat{\Sigma}^{-1}$ is the inverted covariance matrix, and y_i is a column vector of all items for individual i.

Using the analysis approach presented in section 17.3, we will estimate the impact of the intervention on the extent to stigma faced by SPs when presenting as MSM or HIV infected patients relative to the "standard" care experienced by the referent case scenarios of a straight, HIV uninfected man.

3.2 *Secondary Endpoint(s)/Event(s)/Outcome(s):*

Three secondary endpoints will be collected.

The first will take the form of findings from debrief sessions (i.e. structured interviews) with SPs that will be administered by another study team member immediately following each unannounced visit. This qualitative data is intended to identify emergent episodes of adverse care not captured by the healthcare quality checklist used to quantify the primary endpoint. Findings will take the form of a written report to describe patterns and themes emergent in the interviews, with direct quotes to illustrate concepts where helpful.

The second endpoint will be the aggregate clinic-level number of HIV tests conducted in each enrolled clinic during the study period. This data will be abstracted from the provincial case report system.

The third endpoint will be the qualitative data collected through in-depth interviews with our SPs after their participation in each round of clinic visits (baseline and follow-up). The collected data will provide insight into how their sexual identity and experience in community activities may motivate their participation in a research project like ours, and how they may change their views regarding stigma after their study engagement. Findings will take the form of transcribed scripts of recorded interviews.

4.0 Study Intervention(s)/Interaction(s)

4.1 *Description:*

As described in Section 1.1, the main study activities associated with the RCT phase of this project and this protocol involve Stage 1) implementation of the stigma reduction intervention and Stage 2) follow-up data collection using the unannounced SP visit approach.

The main study activities associated with Stage 1 will involve administration of the intervention. The intervention design is largely informed by the Information-Motivation-Behavioral Skills model of behavior change;[36] final details of the intervention design will also be informed by feedback from study team members and each of the two CABs. Information related programming will involve didactic sessions to inform providers on clinical diagnosis and management of common STIs and HIV/STI epidemiology with a focus on its public health impact on marginalized populations including MSM and PLWH. Motivation related sessions will explore providers' intrinsic motivations for practicing medicine and use group discussions to explore their self-perceived roles in addressing the HIV/STI crisis, particularly in socially marginalized groups including MSM. Lastly the behavioral skills sessions will involve both active (role play, group critiques of recorded patient-provider interactions) and passive skills training (watching videos that demonstrate target skills). To reduce travel and time burden on provider participants, the training will be delivered in a hybrid format consisting of both in person, on-site training delivered at the offices of the GDCDC as well as self-directed online units for provider participants to complete on their own within a pre-specified window of time.

The main interactions associated with research activities in Stage 2 involve collection of follow-up data using the same face-to-face surveys and unannounced SP approach as in the baseline visits. The face-to-face survey will be administered by study staff with consented and enrolled providers to collect follow-up data on their attitudes towards working with marginalized populations. In addition consenting providers will have an unannounced SP dispatched to their clinic over the course of the observation period (between 1-3 months from the completion of the stigma reduction intervention) to collect data on observed clinical behaviors. As in the baseline round, SPs will present standardized cases with indications of early stage syphilis infection without informing provider participants that they are incognito patients. Immediately following the visits, SPs will report on the specifics of the encounter by responding to a standardized healthcare quality checklist administered to them by a study enumerator. Enumerators will not accompany SPs into the clinic but will instead wait nearby location such as inside the hired car used for transport to and from clinics. Provider will have been instructed not to confront any patient they suspect may be an SP, and to instead make note of the patient name and visit date. At the conclusion of the follow-up procedures, providers will be given an opportunity to ask whether a particular patient was in fact an SP, findings from which will be included in our study findings as an "SP detection rate."

5.0 Procedures Involved

5.1 *Study Design*

The design of the overall study is a pilot RCT to evaluate the preliminary effectiveness of the stigma reduction intervention developed in the course of the project, with randomization taking place at the facility level (cluster randomization). As activities related to the preparatory phase of research have been completed, the activities described below pertain only to the RCT phase.

5.2 *Study Procedures:*

As described in Section 1.1, study procedures relevant to the RCT Phase (Phase 2) to which this protocol pertains will be divided into the following two stages:

Stage 1: Implementation of the stigma reduction intervention. The intervention will consist of three sections as informed by the Information-Motivation-Behavioral Skills model of behavior change as follows:

1. Information: this unit will consist of substantive information on a) clinical diagnosis and management of common STIs and b) HIV/STI epidemiology with a focus on its public health impact on the MSM population.
2. Motivation: this unit will include sessions exploring providers' intrinsic motivations for practicing medicine and use group discussions to explore their self-perceived roles in addressing the HIV/STI crisis, particularly in socially marginalized groups including MSM.
3. Behavioral skills: these sessions will involve both active (role play, group critiques of recorded patient-provider interactions) and passive skills training (watching videos that demonstrate target skills).

To reduce travel and time burden on provider participants, the training will be delivered in a hybrid format consisting of both in person, on-site training delivered at the offices of the GDCDC as well as self-directed online units for provider participants to complete on their own within a pre-specified window of time.

Stage 2: Follow-up data collection using unannounced SP visits: Immediately following the intervention, staff will conduct clinic visits to administer an in person survey of a shorter version of the baseline survey on their attitudes towards marginalized populations. Within 1-3 months the intervention, SPs will conduct a second round of unannounced clinic visits across the study facilities. As with the baseline visits, providers will not be informed that a particular visit is from an SP. Although all SPs will present to providers a standard case of presumptive syphilis, the case script used in each interaction will be randomly chosen from four slightly different versions that vary only in whether HIV or MSM status is revealed to providers. Draft versions of each of the SP case scripts are in Appendix 3.

The general protocol for SP visits will be as follows: SPs will be paired with an enumerator (members of the study team) to conduct clinic visits. Upon arrival enumerators will wait outside the clinic in the hired car while SPs will present at facilities using the pseudonym in the case script and be processed by clinic in-take staff according to standard local procedures. Before entering the clinic, enumerators will remind SPs of the names of any providers who have not consented to the study. If SPs are offered appointments with a non-consenting provider, they will follow a fixed script indicating their preference for a different "highly recommended" doctor for whose name they will feign a memory lapse. If a visit with a non-consenting provider cannot be avoided, the SP will accept the appointment but abort the visit immediately following intake (a not uncommon occurrence in the local setting). Once presenting to a consented provider, SPs will begin with the opening statement in the script which describes the patient's chief compliant/symptom. SPs will then use standardized language detailed in the case scripts to respond to provider questioning. In interactions where HIV or MSM status will be revealed, SPs will provide this information using standardized language, determined in the formative phase, immediately following the common opening statement. Study staff will accompany occasional SP visits to ensure adherence to protocol and will be available by phone throughout the audit to answer questions or troubleshoot unexpected problems.

As in the baseline study procedures, SPs will exit facilities immediately following the visits and debrief with an enumerator in an area at some distance from the clinic (and most importantly out of earshot of any clinic staff or attendees) where enumerators will administer a health care quality checklist and conduct a debrief session with the SP. The health care quality checklist (Appendix 1) will be administered to SPs in a survey format and collect information on multiple dimensions of care quality including: adherence to Chinese clinical guidelines for syphilis prevention and management, clinical conduct, and communication. Debrief sessions with SPs will be guided by a structured interview guide to ensure each session covers the same content regarding SP perceptions of the clinical interaction.

5.3 *Individually Identifiable Health Information:*

Data collected on provider participants will not include any individually identifiable health information.

6.0 Data Banking

Data will not be banked for this study.

7.0 Sharing of Results with Participants

Although results of the interim analysis (the ROR results) and the results of the full trial have been and will continue to be shared regularly with our CAB members, we will abstain from an explicit sharing of results session with providers. The reason for this is to preserve the integrity of the SP stigma measure and the validity of the intervention evaluation. If providers who participate in this study are made aware of our true research objectives this could give the impression that their superiors at the GDCDC are committed to addressing HIV and sexual stigma, which could in turn influence provider behaviors in future trials. Naturally, such widespread improvement of provider attitudes towards PLWH or MSM would be a welcome if inadvertent change. However given that the ultimate goal of this research is to successfully pilot the proposed intervention in anticipation of an eventual full-scale RCT, maintaining the impression that the research is on generic health services improvement is essential to a valid future trial and eventual real-world implementation of this evaluated intervention.

8.0 Study Duration

8.1 The time span for the full research project (Preparatory and RCT phases) is designed to be achieved in 4 years. The activities associated with stage 1 preparatory phase is finished near the end of the second study year. Stage 2 which involves intervention development, intervention run, follow-up survey and follow-up SP clinic visits is anticipated to take 15 months, followed by 9 months to conduct data analysis.

8.2 The time span for the qualitative sub-component will be from the initial to the follow-up round of interviews, a time span of about 1 year.

Deleted: Measures pertaining to data banking have not yet been implemented given pending guidance from IRB experts. A separate modification will be submitted at a separate time addressing this component.

Deleted: All the collected data will be de-identified and stored in the Box Secure Storage. Data involving personal identifiable information will be saved in password encrypted folders. Its access is only granted to project researchers.

Deleted: Considering the project needs and the challenge of re-approaching the participants, the de-identified datasets will not be shared through any data depositories. ¶
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9.0 Study Population

9.1 *Inclusion Criteria:*

Randomization of provider participants took place at the facility level (clutser-RCT); as such inclusion criteria are provided for both facilities and providers. Eligible facilities were those with 1) formal government accreditation as a medical center (a basic tenet of all public hospitals in China); and 2) possession of an accredited on-site laboratory with capacity to provide enzyme-linked immunosorbent assay testing for HIV, treponemal (e.g. Treponema pallidum particle agglutination) and non-treponemal tests (e.g. rapid plasma regain) for syphilis. Within eligible and consenting facilities, eligible providers are those who are licensed at the time of the study to practice dermatovenereology in China.

Note that individuals recruited to participate in study activities are considered part time study staff and so are not subject to formal inclusion or exclusion criteria. Guidelines regarding recruitment and hiring strategies for SPs are detailed in internal protocols detailing the SP visits approach to stigma measurement.

Participants of the qualitative sub-study will be any SP who took part in the baseline round of unannounced clinic visits. Their participation in the sub-study is fully voluntary and will not affect their eligibility to continue work as an SP in the main study.

9.2 *Exclusion Criteria:*
None

9.3 *Screening:*

Facility level screening took place at the time of facility enumeration and sampling to ensure that only facility directors of eligible practices were approached for study participation. Records on the institutional details for each facility are maintained by the GDCDC and were used to identify eligible clinics. All active providers at eligible facilities were assumed to have up to date medical licensure, which was confirmed by study staff at the time of baseline procedures (in-person recruitment, enrollment, and consent).

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10.0 Vulnerable Populations

10.1 *Vulnerable Populations:*

Population / Group	**Identify whether any of the following populations will be targeted, included (not necessarily targeted) or excluded from participation in the study.**
Children	Excluded from ParticipationExcluded from ParticipationExcluded from ParticipationExcluded from Participation

Pregnant women/fetuses/neonates	Included/Allowed to ParticipateIncluded/Allowed to ParticipateIncluded/Allowed to ParticipateIncluded/Allowed to Participate
Prisoners	Excluded from ParticipationExcluded from ParticipationExcluded from ParticipationExcluded from Participation
Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders	Excluded from ParticipationExcluded from ParticipationExcluded from ParticipationExcluded from Participation
Non-English speakers	Targeted PopulationTargeted PopulationTargeted PopulationTargeted Population
Those unable to read (illiterate)	Excluded from ParticipationExcluded from ParticipationExcluded from ParticipationExcluded from Participation
Employees of the researcher	Excluded from ParticipationExcluded from ParticipationExcluded from ParticipationExcluded from Participation
Students of the researcher	Excluded from ParticipationExcluded from ParticipationExcluded from ParticipationExcluded from Participation
Undervalued or disenfranchised social group	Excluded from ParticipationExcluded from ParticipationExcluded from ParticipationExcluded from Participation
Active members of the military (service members), DoD personnel (including civilian employees)	Excluded from ParticipationExcluded from ParticipationExcluded from

	ParticipationExcluded from Participation
Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.	Excluded from ParticipationExcluded from ParticipationExcluded from ParticipationExcluded from Participation
Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare.	Excluded from ParticipationExcluded from ParticipationExcluded from ParticipationExcluded from Participation
Individual or group with a serious health condition for which there are no satisfactory standard treatments.	Excluded from ParticipationExcluded from ParticipationExcluded from ParticipationExcluded from Participation
Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior).	Targeted PopulationTargeted PopulationTargeted PopulationTargeted Population
Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research.	Excluded from ParticipationExcluded from ParticipationExcluded from ParticipationExcluded from Participation

10.2 *Additional Safeguards:*

Provider participants in our study may be considered a group with a justified fear of negative consequences for not participating in the research. As in other professions, medicine in China is a relatively hierarchical field in which junior level physicians generally follow orders of their superiors. Therefore if a facility director has issued consent for his/her facility to take part in the study, some providers may feel an implicit pressure to take part in the study even if against their will. Some may fear retribution (e.g. pay cut, demotion) from their superiors for refusal to participate in research. To ensure that our providers are protected from either of these risks we will take the following precautions.

To minimize the risk of providers feeling pressured to participate in the study against their will, we explained the importance of voluntary participation to all facility directors in the course of facility-level recruitment procedures. In addition, all in-person study activities (recruitment, consent, survey administration) were

conducted in private office spaces out of sight from colleagues and directors. Study staff assured providers that information about their participation would not be shared with anyone else at the facility. All approached providers—particularly those who refuse to participate—were provided with a copy of the unsigned consent form to ensure they had contact information for our local study manager, Dr. Cheng Wang of the GDCDC in case of any concerning events following study initiation. In the event study staff suspect coercive participation, Dr. Ligang Yang was designated as the first study team member who would reach out first to the provider and then to the facility director in order to investigate the issue and mediate a resolution. Two reasons that we feel risk of coercion is low is that 1) medical facilities in China are expected to generate a large share of their operating costs through hospital revenues and so are financially independent of oversight organizations. The GDCDC itself provides only oversight and technical capacity. Therefore facility directors do not necessarily feel institutional pressure from Dr. Ligang Yang to consent to study participation. By extension, facility directors are also unlikely to feel that they have anything personally to gain from ensuring that all of their providers take part in the study. Second, given the growing demands for modern medical care in China, qualified doctors are currently in short supply, making it unlikely that supervisors would seek retribution on their medical personnel for reasons as minor as study participation.

An additional factor that could contribute to provider participants' vulnerability is the fact that our study collected data on their behaviors including potentially discriminatory or stigmatizing behavior towards patients. If data on these adverse interactions are to get leaked, this could generate negative press for the provider or the facility and even form grounds for a medical malpractice suit. We therefore have and will continue to take the following precautions to protect the identity of provider participants and to ensure the security of data collected throughout the study. First, all study staff including SPs and enumerators have undergone human subjects/research ethics training, including the need for complete data protections and anonymity. All US-based Principal Investigators/Co-Investigators and China-based GDCDC staff have taken and passed the CITI training courses in Research Ethics/Human Subject Protection. Second, all data collection procedures that follow each unannounced SP visit were conducted wit the use of a unique study ID number to identify both the provider participant and the study facility, linkage files for which are only accessible to senior study staff and the co-PIs. Debriefings between SPs and enumerators for the purposes of data collection have been and will continue to be conducted in a private location such as a park bench at a safe distance from the facility. All data has been and will continue to be collected on encrypted tablet or laptop computers and transferred only via Box Secure Storage unsecure transfer of information online (details on Box provided in Section 18.1). All study information has been and will continue to be de-identified as soon as possible after collection. Lastly, any breaches of confidentiality or unanticipated problems that occur during the study will be brought to attention of the two co-PIs who will notify the IRBs of the University of Minnesota and GDCDC for further review and action. No presentation or publication of the study results will refer to participants individually.

Please note that members of other vulnerable populations—namely MSM and PLWH—take part in this study as CAB members and SPs. Protocols and procedures are in place to ensure protection of their identities and to minimize any undue risk as a result of taking part in this study. However as they are

considered advisers and members of the study staff, detailed discussion of their safeguards are not described in this protocol.

11.0 Number of Participants

11.1 *Number of Participants to be Consented:*

To demonstrate the preliminary effectiveness of the intervention we recruited approximately 20 facilities within which an estimated 8 eligible providers work. For the baseline visits a total of 160 unannounced SP visits were made, or about 8 visits per clinic. Given the nature of patient intake procedures at outpatients facilities of the type that our SPs will visit, we were unable to control which of the consented providers in a given facility consented to SP visits. It is therefore possible that some consented providers in these clinics will never receive an unannounced SP visit, while others may receive multiple visits.

12.0 Recruitment Methods

12.1 *Recruitment Process:*

Sampling of study facilities will take place across the 46 candidate STD practices across the Guangzhou metro area (Fig 2) and which meet our eligibility criteria of 1) having formal government accreditation as a medical center (a basic tenet of all public hospitals in China); and 2) possession of an accredited on-site laboratory with capacity to provide enzyme-linked immunosorbent assay testing for HIV, treponemal (e.g. Treponema pallidum particle agglutination) and non-treponemal tests (e.g. rapid plasma regain) for syphilis. Sampling will be conducted using a stratified approach to sample evenly across the 11 districts of Guangzhou city which includes urban and rural areas in order to maximize comparability between arms. Sampling will also consider travel distance between study facilities in order to minimize risk of contamination across arms following the intervention. Lastly, twice the number of facilities as needed for the final sample size will be screened and randomized in anticipation of the fact that a subset of facilities may refuse to take part in the study. Following randomization of sampled clinics, we will implement an additional randomization scheme to balance the distribution of the four SP scenarios (MSM only, HIV+ only, MSM and HIV+, and non-MSM HIV- man) and the 8 different SPs across the 20 study clinics. The scheme will also ensure that case scenarios and SP choice will be distributed over the clinic visit duration to balance the potential effects of these design features on our outcome measurement.

Recruitment took place in a staged manner, first at the facility level and then at the provider level. Following sampling and randomization of facilities to the treatment versus control condition (see Section 22.0 for justification of the randomization approach), facility directors of the chosen sites were contacted by Dr. Ligang Yang, a co-investigator on this study and Director of the STD Clinical Quality Control Program at the GDCDC, as well as officials at a subsidiary organization at the Guangzhou City STD Control Center (GZCDC). STD control officials at the GZCDC report to their counterparts at the GDCDC for all matters pertaining to surveillance, disease control, and intervention work. Both Dr. Yang and his subordinates at the GZCDC maintain regular contact with administrators

of eligible health facilities in the sample pool who they contacted by phone to explain study objectives and procedures (in which the study will be referred to generically as a “healthcare services survey”) and obtained verbal confirmation of their understanding of the following study activities and expectations: 1) permission for study staff to approach individual providers in their facility for recruitment; 2) access by study staff to names and contact information of all providers; 3) for access to facility-level data (e.g. clinic size, average salary, etc.) to be used in the final analysis; and 4) for facilities randomized to the treatment arm to invite providers to participate in the hybrid intervention workshop. Given the burden of work on one person (Dr. Ligang Yang), these verbal confirmation procedures were conducted over the phone and via Wechat messaging. Content of the conversation and items discussed were documented on a per-call basis using the template in Appendix 2.

In a second recruitment round, study staff approached providers in person at consenting facilities to conduct individual level recruitment. Suitable times to visits providers (e.g. during lunch time, at the end of day) were discussed in advance with facility directors. Once at the clinic, study staff described the study objectives—described once more as a “healthcare services survey”)—and sought written consent to 1) administer an face-to-face survey during the same visits; 2) to receive an SP visits at some time over the next 3 to 6 months; and 3) among providers at facilities randomized to the treatment condition to take part in a hybrid professional skills building workshop. Providers were assured that their participation in any part of the study would be fully voluntary and that neither their decision to participate nor their study data would be shared in any form with their clinical director. Providers who could not be reached in person at the time of staff visits to the facility were contacted by phone using contact information provided during facility-level recruitment procedures. The names of providers who declined to give their consent for study participation were included on a secure list in order to inform SP-facilitator teams of specific providers to avoid during unannounced visits. Assignment to a specific provider usually takes place during intake procedures, at which point SPs were able to avoid seeing a particular provider either by expressing a preference for a different provider, not recording information during the visit, or terminating the visit if necessary.

Both clinic directors and provider participants themselves were provided contact information to follow up with the study team if needed. For this role we relied on Dr. Cheng Wang who oversees epidemiological research at the GDCDC. He is of equal rank to Drs. Ligang Yang and Bin Yang who both oversee clinical care standards, but is also seen as independent of the other two administrators so can therefore be a resource for participants in the event of concerns or questions. Dr. Wang is also well versed in the details of this study and well positioned to answer questions. To maximize security of the email account which participants may use to contact Dr. Wang, we used the following ProtonMail account, GDDH@protonmail.com. ProtonMail is a secure email service with end-to-end encryption and is HIPAA compliant (see https://protonmail.com/hipaa-compliance). This email has been monitored by Dr. Wang as well as the two co-PIs, Drs. Kumi Smith and Sean Sylvia.

Though not considered study subjects, two CABs were also assembled to provide key input into the design and conduct of our research. One is composed of providers and another of MSM. Each CAB is composed of 5-10 members.

Providers were recruited (after sampling selection of study facilities) by the GDCDC from among providers not in consenting facilities but providing outpatient care for STIs elsewhere in Guangdong. To ensure that provider CAB members feel free to share their opinions freely, we recruited members of equivalent or similar professional rank. Members of the MSM CAB were recruited with the help of Zhitong LGBT Center, a community organization serving MSM in Guangdong. The former director of operations at Zhitong, Danyang Luo, is now a study team member for this grant. With Mr. Luo's guidance, Zhitong solicited candidates through postings on social media (internal to Zhitong members) and by word-of-mouth. Those expressing interest were then followed up by study staff via phone to explain study objectives, CAB member responsibilities, and expenses covered by the study (travel, lodging per diem). Candidate members were individuals active in the MSM community with experience in areas such as community organizing, health promotion, LGBT advocacy, or research. We purposively recruited at least 1/3 of members from the community of people living with HIV (PLWH) so as to ensure their input into the design of the study and intervention which ultimately seeks to improve outcomes for this group. Those who are living with HIV were informed in advance that participation in the CAB could entail disclosing their status to other members. We did not anticipate this to be a deterrent for participation, as other candidate CAB members are all MSM active in this space and who therefore are deeply familiar and sympathetic to the issues and concerns of HIV+ MSM in their community.

SPs for the qualitative sub-study will be approached by study staff via Wechat message which is the primary form of communication for most study affairs between study staff and SPs. The study will be introduced as a sub-study to learn more about their experiences as individuals taking part in an SP study. They will be told the duration of the study: 2 interviews, each no longer than an hour, taking place once after completion of training and once after completion of the baseline round of visits. They will be informed that each interview is voluntary and that participation – whether in both, one, or neither interview – will not affect their work as an SP.

12.2 *Source of Participants:*

Provider participants are any clinical staff licensed to provide dermatovenerological care in China. Because this is a cluster randomized trial and study eligibility is initially assessed at the facility level, these institutions have been the primary source of participants.

SPs for the qualitative sub-study will include any of the SPs already hired, trained, and actively working for the study. Those who leave the study early will still be approached for interview opportunities.

12.3 *Identification of Potential Participants:*

Study practices were sampled from the 46 STD practices across the Guangzhou metro area and which met our inclusion criteria as described in section 12.1. Potential members for the provider CAB were identified by co-GDCDC co-investigators who maintain regular communication with directors of all member practices within the provincial STD clinical network. Potential members of the

MSM CABs were identified and approached by Mr. Luo of the Zhitong LGBT Center, then followed up by study staff using the same procedures as with providers.

12.4 *Recruitment Materials:*

Recruitment materials pertaining to the Preparatory phase of the project included 1) script to be read by Dr. Ligang Yang in the process of obtaining verbal confirmation of study procedures from facility directors and 2) script to be read by study staff in the process of in person recruitment and consenting of providers. According to our decision to use the modified Zelen design for our RCT (see details in Section 22.0), details of the recruitment text varied slightly depending on whether recruitment is occurring at a facility randomized to the treatment versus the control condition.

12.5 *Payment:*

Commented [KS1]: Add compensation for completing the intervention training.

In phase II, providers who are randomized to the treatment arm will take part in a professional skills building workshop as part of the intervention condition. All costs associated with workshop participation including lodging will be covered by the study budget. In addition to these costs, participants of the workshop will be provided study compensation for completing the pre-workshop videos, and attending the in-person training (42 dollars / 300 RMB compensation for each participant). These compensation amounts have been deemed necessary by the local team members based on historic challenges of sustaining adequate attendance by providers who have many competing demands for their time. Immediately after the intervention, staff will conduct clinic visits to survey the provider participants. Both control and treatment arms participants who finish the follow-up survey will receive 50 RMB (about 7 USD) compensation.

SPs for the qualitative sub-study will receive 150 RMB (about 24 USD) for the first round of interviews and 50 RMB (about 7 USD) for the second round.

13.0 Withdrawal of Participants

13.1 *Withdrawal Circumstances*

Any participant wishing to withdraw from the study for any reason is permitted to do so at any point in the study.

13.2 *Withdrawal Procedures*

Once intention to withdraw or to be withdrawn has been confirmed, study staff will initiate discussion with participants about their wishes regarding retention of data they have already contributed to the study. Withdrawing participants will be offered a choice between having their data retained or discarded from the remainder of study proceedings. They will also be informed that aggregate information about the facility at which they work or about colleagues working at the same facility will still be used as part of the planned analysis.

13.3 *Termination Procedures*

We do not anticipate many circumstances in which study investigators would need to terminate a participant from the study. Barring any harm to participants, termination may also be considered if participant continuation threatens

successful implementation of the study. The most plausible scenario for which our team will be prepared are cases when a provider, suspecting a certain patient is an SP, may choose to confront the SP during an unannounced clinic visit. This would not directly harm the provider nor the SP, but may signal to the study team that the provider's participation may be jeopardizing the quality of care received by the provider's other patients. In such an event the SP and the co-PIs will discuss the episode and it's possible effects on the participant and those around him/her. A final decisions around termination will be jointly made by the co-PI's, who may also consult the provider CAB for guidance in the matter if deemed necessary. As with withdrawal procedures, terminated participants will be offered a choice between having their data retained or discarded from the remainder of study proceedings. They will also be informed that aggregate information about the facility at which they work or about colleagues working at the same facility will still be used as part of the planned analysis.

14.0 Risks to Participants

14.1 *Foreseeable Risks:*

Provider participants in our study may be considered a group with a justified fear of negative consequences for not participating in the research. As in other professions, medicine in China is a relatively hierarchical field in which junior level physicians generally follow orders of their superiors. Therefore if a facility director has issued consent for his/her facility to take part in the study, some providers may sense unspoken pressure to take part in the study even if against their will. Some may fear retribution (e.g. pay cut, demotion) from their superiors for refusal to participate in research. To ensure that our providers are protected from either of these risks we have and will continue to take the precautions listed in Section 10.2.

An additional factor that may make our provider participants vulnerable is the fact that our study collects data on their behaviors including potentially discriminatory or stigmatizing behavior towards patients. If data on these adverse interactions are leaked, this could generate negative press for the provider or the facility and even form grounds for a medical malpractice suit.

Details on the measures to be taken to minimize these risks are detailed in Section 10.2.

Foreseeable risks to SPs taking part in the qualitative sub-study may include psychological duress experienced from recalling unpleasant experiences during their participation in this study or in recalling experiences of discrimination from their personal life.

14.2 *Reproduction Risks:*

N/A

14.3 *Risks to Others:*

There is a possibility that providers working at facilities randomized to the control arm may perceive an inequity in their assignment and alter the quality of care they provide to their patients. To minimize this risk we have adopted the modified Zelen design in which participants randomized to the control arm are not informed of their assignment or that the study is a randomized trial. Conversely patients of providers randomized to the treatment arm may receive better-than-standard care quality as a result of their providers' awareness of the study objectives. This may ultimately result in an unintended *benefit* for these patients. To minimize the impact of such effects on the unbiased estimation of program impact, however, we are taking many precautions to mask the true objectives of the study from participants and rather describe it as generic research on "health services."

15.0 Incomplete Disclosure or Deception

15.1 *Incomplete Disclosure or Deception:*

In order to preserve the scientific validity of our main study outcome (stigma) and to minimize risk of unintended behavior change in the control group due to knowledge of the treatment condition, our consent procedures involved the two distinct forms of deception detailed below. Guided by the principles of respect for persons and beneficence from the Belmont Report, we centered our design on the goal of maintaining minimum necessary levels of deception and prioritizing participant well-being in all study procedures.

In order to preserve the integrity of our primary outcome measure—HIV and sexual stigma on the part of medical providers towards their patients—we hav and will continue to abstain from any reference to stigma in all participant interactions. Instead, all reference to the study and its objectives has been and will continue to be couched in the language of generic research on "patient-centered care." The justification for this approach is to avoid alerting participants to the notion of healthcare stigma, which could induce altered behaviors under observation. Doing so would not only undermine our ability to observe and learn from typical clinical behaviors but would also interfere with our ability to conduct an unbiased evaluation of our stigma reduction intervention. In addition, SP visits to observe provider behaviors are only partially unannounced; that is, providers are informed of the time range during which an SP visit will happen but not of the exact day or which patient is an SP. The justification for this approach is to reduce risk of SP discovery by providers and maximize our ability as researchers to observe true clinical behaviors. Providers are given opportunities at the end of the study to guess which patients may have been SPs in order to test the validity of our stigma measure. Past uses of the unannounced SP visit model by co-PI Dr. Sean Sylvia have reported discovery rates of 7%.

A second instance of deception in this study is the masking of the randomized nature of the study to facilities and providers in the control arm. This approach, the modified Zelen design,[37,38] can be considered ethical in instances when the intervention is not considered to be therapeutic or potentially life-saving. It can be also be considered justifiable if used to mitigate inadvertent altering of behaviors by individuals in the control arm due to their awareness of the treatment condition. Moreover if these altered behaviors have the potential to disadvantage their patients in terms of the quality of care they receive during the study, the

modified Zelen is even further justified. At the close of the study we will refrain from revealing the randomized nature of the study in order to preserve ideal conditions an anticipation of a fully powered RCT to follow this pilot study. In the event that control arm providers learn of the intervention (a hybrid professional skills building workshop) through their personal networks and confront study investigators or coordinators, the event will be explained to them as an experimental training that the GDCDC is piloting for potential future scale up.

16.0 Potential Benefits to Participants

Provider participants randomized to the treatment arm will benefit from the opportunity to take part in the stigma reduction intervention. Those randomized to the control arm will not access this benefit. However they may gain indirect benefits in the form of contributing the development and evaluation of an intervention to reduce the incidence of stigmatizing and discriminatory behavior towards PLHA and MSM in Chinese medical settings. If found effective, the intervention developed in the course of this study may be adopted by provincial policy makers (our co-investigators at the GDCDC) and incorporated into routinized clinical training throughout the provincial network of DV practices. The model for measuring and addressing enacted healthcare stigma developed in the course of this study will also be documented and disseminated with the intention for it to be replicated in other settings, particularly in low/middle-income settings that bear the greatest burden of HIV worldwide and where stigma is most severe.

SPs taking part in our qualitative sub-study may benefit from the interviews by having an opportunity to share their personal experiences with the study team or air any grievances about study conduct.

17.0 Data Management

17.1 *Data Analysis Plan:*

The primary goal of the study is to estimate the impact of healthcare stigma—in particular stigma directed at patients living with HIV (HIV stigma), patients who have same sex behaviors (homophobia), and patients with both attributes (intersectional stigma) on the quality of sexual healthcare they receive. Stigma is quantified as the difference in the mean healthcare quality index across the four case scenarios. Patterns of stigma occurrence are also assessed by stratifying results across key attributes such as tier of care (e.g. county hospital versus township clinic), rural/urban region, provider sex, and provider professional rank in order to illuminate provider subgroups of interest to inform tailored intervention design. A secondary analytical goal of this study is to assess the preliminary effect of the intervention on healthcare quality by comparing the same healthcare quality index across treatment arms. Details in the power analysis (section 17.2) and statistical analysis (section 17.3) sections are described separately for these two gaols.

For the qualitative sub-study analysis, data from debrief session conducted with SPs following each clinic visits will be transcribed and translated into English by study staff and spot checked by the co-PIs for transcription accuracy by bilingual

study staff. Co-PIs will oversee analysis by study staff including coding of transcripts and identification and interpretation of emergent themes.

17.2 *Power Analysis:*

Stigma Quantification: The primary objective of this pilot study is to estimate the extent to which stigma towards PLWH (HIV stigma) and towards MSM (homophobia) contribute to the deterioration of healthcare quality relative to straight people without HIV. A total sample size of 160 standardized patient (SP) interactions would provide 80% power (alpha=0.05) to detect a minimum effect size of 0.18 standard deviation. This calculation is conservative in that it does not account for blocked randomization of the SP cases within practices, which will lend additional power to each comparison. Two-sided tests will be needed to detect differences across the four case scenarios in order to separately quantify HIV, sexual, and intersectional stigma, for which the same assumptions will provide the same amount of power to identify a minimum effect size of 0.17 standard deviation between any 2 pairwise comparisons of scenarios. As recruitment will take place at the clinic level, the number of participants that will be needed to be recruited to the study will depend on estimates of the average numbers of eligible providers that our team can reasonably expect to recruit at each clinic. Preliminary data suggest that clinics in our study region employ an average of 5 eligible providers, of whom we conservatively expect to recruit 70% or 3.5 per clinic. Each provider will receive 3 unannounced visits from a standardized patient, yielding a final estimated pool of 56 providers for this study.

Preliminary intervention effects: A secondary goal of the RCT is to estimate the preliminary effect of the intervention on quality of care index observed by SPs. Though this is only a secondary goal, we determine that it is plausible that the target enrollment of 20 clinics randomly allocated to treatment and control in a 1:1 manner could yield sufficient power to detect reasonably small effects on the primary outcome measure. That is, with an alpha level of 0.05 for a one-sided test, an intra-cluster coefficient of 0.07, and a baseline prevalence of standardized quality of care index (with mean of 0 and standard deviation of 1), a sample size of 160 SP clinic visits (8 visits per clinic on average) would provide 80% power to detect a reduction in EOC scores due to the intervention as small as 0.17 standard deviations.

17.3 *Statistical Analysis:*

Stigma Quantification: Each of the four SP scenarios will be coded across two binary variables (“MSM” and “HIV”) that will separately account for whether same-sex behaviors, HIV+ status, or both were announced by the SP during the provider visit. The scenarios will then be regressed on the quality of care index to assess the excess erosion of care observed in visits where SPs present as both HIV infected and as MSM, beyond the simple sum or product of the erosion experienced with only one of the attributes. Specifically, we will estimate:

$$\theta_{ijs} = \alpha + \beta_1 HIV_{ij} + \beta_2 MSM_{ij} + \beta_3 (HIV_{ij} * MSM_{ij}) + \gamma_j + \eta_s + \varepsilon_{ijs}$$

where θ_{ijs} is the quality of care index as measured in SP interaction i in facility j conducted by SPs; HIV_{ij} is an indicator for the HIV status of the SP scenario in that given provider encounter; MSM_{ij} an indicator for the MSM status of the SP scenario in that given provider encounter; γ_j is a vector of facility fixed effects; and η_s is a vector of fixed effects for SPs. Here, β_1 and β_2 provides an estimate of HIV and

MSM stigma respectively, and β_3 the estimate of stigma due to the presence of both HIV and MSM status.

Preliminary intervention effects: We will estimate the main intention-to-treat (ITT) impact of the training intervention using the Ordinary Least Squares (OLS) regression:

$$\theta_{idc} = \beta_0 + \beta_1 T_c + \beta_2 \overline{\theta}_{dc(t-1)} + \gamma X_{ic} + \varepsilon_{idc}$$

where θ_{ict} is the healthcare quality index from SP interaction *i* with doctor *d* in clinic *c* measured at follow-up, T_c is a dummy variable that takes the value of 1 if the clinic was randomized to be offered training and 0 if in the control group. The coefficient of interest is β_1, which captures the ITT effect of training on the quality of care. We control for the average quality index from all SP interaction with doctor *d* at baseline, $\overline{\theta}_{dc(t-1)}$, as well as a vector of SP and disease script type (varying HIV and MSM status) fixed effects. ε_{idc} represents the idiosyncratic error, which we cluster at the clinic, the level of randomization.

The ITT impacts reflect the effect of physicians being *offered* an opportunity to participate in training, not the causal effect of training itself. We therefore also estimate the effect of participating in training using the model

$$\theta_{idc} = \pi_0 + \pi_1 A_{dc} + \pi_2 \overline{\theta}_{dc(t-1)} + \varphi X_{ic} + \nu_{idc}$$

where $A_{dc}$is a measure of whether or not doctor *d* in clinic *c* attends the training and other variables are defined as above. We fit this equation by two-stage least squares (2sls) using the following first-stage equation:

$$A_{dc} = \delta_0 + \delta_1 T_c + \delta_2 \overline{\theta}_{dc(t-1)} + \zeta X_{ic} + \mu_{idc}$$

where the excluded instrument is the treatment assignment of doctor *d*'s clinic, T_c. We interpret the coefficient π_1 as the local average treatment effect, or LATE, of participating in training on the quality of care provided.

While the analysis outlined above provides estimates of the effect of the training (or offer of training) on the quality of care provided to SPs presenting with cases of presumptive syphilis, the goal is to estimate the effect of the training on *enacted stigma*. That is, rather than the overall effect on the level of healthcare quality, we are primarily concerned with observing how the training affects the difference in the quality of care received by patients presenting as MSM or HIV-positive vs. those not, all else equal. Our two levels of randomization (SP-doctor interactions disease script types and clinics to treatment or control) allow us to estimate the causal effect of training offer (or participation) by estimating regressions analogous to the above, but interacting the dummy clinic treatment allocation with dummy variables for each SP script type. For ITT effects, we estimate

$$\theta_{idc} = \alpha_0 + \alpha_1 T_c + \alpha_{11} T_c \times V^{HIV+,MSM-} + \alpha_{12} T_c \times V^{HIV-,MSM+} + \alpha_{13} T_c \times V^{HIV+,MSM+} + \alpha_2 \overline{\theta}_{dc(t-1)} + \gamma \Gamma_{ic} + \varepsilon_{idc}$$

Where V are dummy variables for three of the four script variations (leaving out the HIV-, MSM- variation). Γ_{ic} is a vector of SP fixed effects. The coefficients $\alpha_{11} - \alpha_{13}$ represent the effect of training offer on the *difference* in healthcare quality provided

to SPs presenting as {HIV+,MSM-}, {HIV-,MSM+}, and {HIV+,MSM+} compared to {HIV-,MSM-}.

17.4 *Data Integrity:*

Protocols will be in place to ensure the quality of the data collected. First, all survey data, whether from face-to-face interviews with providers or in the process of post-visits data collection with SPs, will be collected using Wenjuanxing (https://www.wjx.cn), a free data collection software program widely used in social science research in China. The program is optimized for Chinese language display and for administration using either desktop, tablet, or mobile devices. It features built in quality control mechanisms including skip patterns and answer validation. Although the team used Survey Solutions, a free program developed by the World Bank in the first round, several issues with program glitches led to local experts to advise our migration to Wenjuanxing instead.

Regardless of the software program, use of computer-assisted personal interviewing (CAPI) techniques reduces errors in data collection by automating skip patterns and allowing for the pre-specification of rules to reduce the incidence of implausible and missing values. CAPI also improves data quality by eliminating errors that occur when data are input from physical forms.

Second, all enumerators will be extensively trained using well-defined data collection protocols. Enumerator training aims to standardized survey protocols including the presentation of questions to reduce variability due to differences in survey administration.

Finally, data management protocols are specified to ensure data integrity after collection. These include specified conventions for storage & backup, database construction, naming conventions, and documentation.

18.0 Confidentiality

18.1 *Data Security:*

Since provider names, place of employment, and other indirect identifiers (medical training, age, sex) will be collected, there is a risk that a breach of data security could lead to identification of study participants. To minimize the risk of confidentiality breaches in the course of data collection on providers and patients (aggregate clinic-level testing volume), all study staff will receive training on data security methods. All data will be collected on encrypted tablet computers and transferred via encrypted connection to Box Secure Storage, a secure environment featuring encryption, activity logging, Duo Two-Factor Authentication, and access controls such as view-only access. Created by the Center of Excellence for HIPAA Data and supported by the University of Minnesota, access to relevant Box storage files will maintained by co-PI Dr Kumi Smith and granted to authorized study staff. In addition

All study information will be stripped of direct identifiers as soon as possible, and we will consult with data curators at the University of Minnesota for support to minimize presence of indirect identifiers. No individually identifiable data will be collected in the course of CAB proceedings. Data from provider surveys and SP interactions will be de-identified once survey and SP interaction data have been merged by replacing provider names with identification codes (names are required

to verify the merge). In addition results of a HIPCO Compliance Review Survey have been completed and submitted to the IRB of the University of Minnesota.

Privacy laws in China are not anticipated to impact protections of our study data given the local legal context and the lack of local legal enforcement capacity. We will instead rely on our local site PI Dr. Bin Yang in her capacity as head of the provincial STD health authority (as well as her colleagues in the provincial health bureau) to adjudicate privacy issues raised in the course of study procedures.

Audio recordings of in-depth interviews collected from SPs as part of our qualitative sub-study will be stored on password protected study devices before being uploaded to the Box cloud. Recordings will be transcribed by study staff, after which audio recordings will be destroyed. All digital files will be stored with study-specific identification numbers; files containing participant names will be stored separately in a password protected file.

19.0 Provisions to Monitor the Data to Ensure the Safety of Participants

19.1 *Data Integrity Monitoring.*

Study implementation will be monitored by the MPIs and the primary GDCDC Co-I. Study monitors will conduct reviews at each study phase to:

- Assess adherence to the study protocol including implementation, recording, and reporting;
- Verify compliance with human subjects and other research regulations and guidelines;
- Confirm the quality and accuracy of information collected at the study site and recording in the study database.

At each study milestone, the three monitors will meet to review protocol compliance and data integrity. During study implementation the GDCDC co-I will conduct monitor onsite. Any deviations from protocol will be documented in a report at each study milestone. In addition to noting protocol deviations, this report will describe actions taken to respond to deviations. These actions will be determined by the MPIs on a case-by-case basis. Monitoring documents will be kept as part of the permanent study record.

19.2 *Data Safety Monitoring.*

The study will not entail continuous data collection on participants. As such no protocols for continuous data safety monitoring are believed necessary.

20.0 Provisions to Protect the Privacy Interests of Participants

20.1 *Protecting Privacy:*

We will take several measures to ensure the privacy of providers receiving SP visits. Data collected during visits will be identified by a study ID only, and the key linking the study ID to direct identifiers (e.g. name) or indirect identifiers (i.e. combination of variables such as facility name, provider age and sex) will be stored in separate password protected documents stored on encrypted tablet or laptop computers and transferred only on encrypted USB drives. Direct and indirect identifying information regarding providers will only be used to navigate logistical procedures during SP visits and will be destroyed following the follow-up SP visits.

In addition, debriefing sessions conducted between SPs and facilitators after each clinic visit will be conducted in a private location such as hired car or park bench away from the facility.

To maintain the privacy of CAB participants, meetings will take place in private locations and meeting transcriptions will not include any information linking statements or ideas expressed to individual CAB members. Within 72 hours following each session, two study team members will review meeting notes and verify content against recordings where necessary. Following this review, session recordings will be destroyed/permanently deleted. In addition, prior to the start of each meeting, principles of conduct including the importance of privacy and confidentiality will be emphasized to all participants. If so desired, participants of any of the CABs will also be invited to pick a pseudonym for use for the duration of their CAB participation for the protection of their privacy within the group.

20.2 *Access to Participants:*

The research team will not access medical records or any other sources of private information about the participants.

21.0 Compensation for Research-Related Injury

21.1 *Compensation for Research-Related Injury:*

N/A

21.2 *Contract Language:*

N/A

22.0 Consent Process

22.1 *Consent Process:*

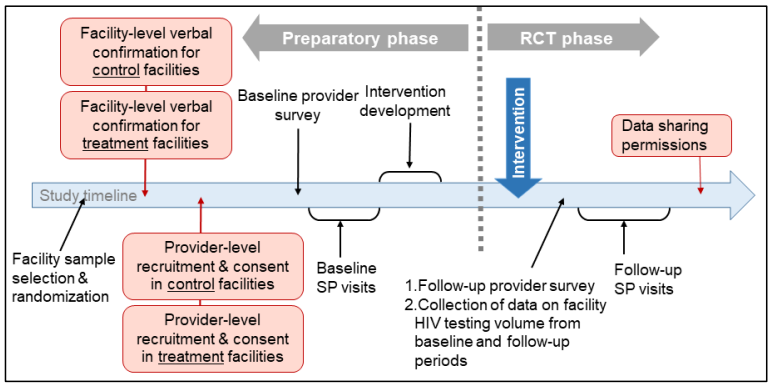
All provider participants in this study were recruited, consented, and enrolled in the first phase of the study. Therefore no consent procedures are involved in this stage of the research. Upon administration of follow-up provider surveys and follow-up SP visits, however, we will seek permission from providers to share their de-identified data as part of post-study data release procedures. Participants will be offered a tiered choice of data release procedures including a publicly available repository (i.e. the Data Repository of the U of M) or a repository where access is locked behind a vetting process regulated by the co-PIs (e.g. ICPSR or Dataverse). The justification for separating the consent procedures for study participation and data sharing permissions is in order to minimize the impact of decisions about data sharing on study participation. Documents pertaining to data permissions procedures will be added / modified at the commencement of the RCT phase of the project.

Below is a description of the original consent procedures used in the first phase of the study:

In order to minimize risk of unintended behavior change in the control group due to knowledge of the treatment condition, our consent procedures will involve a modified Zelen RCT design.[39,40] A schemata of consent procedures for the entire

study (i.e. the Preparatory phase and RCT phase) are provided in Figure 1. Note that for the sake of context, the description below describes consent procedures for the entire study including both the preparatory and RCT phases; however, the protocol itself only pertains to the preparatory phase up until implementation of the intervention.

Figure 1. Schemata for informed consent procedures in the context of study proceedings.



According to the modified Zelen design, randomization will take place immediately after enumeration and sample selection, but before formal consent has been obtained. Following randomization, our collaborators at the GDCDC will implement verbal confirmation procedures with directors of eligible health facilities in both the control arm and treatment arms. In both arms, this consent process will involve explanation of study objectives and procedures (in which the study will be referred to generically as a "healthcare services survey") and will seek explain the relevant study activities to which interested providers in their facility will be asked to consent (note that the list of activities described to control arm directors will not mention the intervention activities in line with the modified Zelen design). In addition, directors will be asked to provide our study stuff with names and contact information of all providers in their facility as well as access to facility-level data (e.g. clinic size, average salary, etc.) to be used in the final analysis. Verbal confirmation procedures with facility directors will be conducted by Dr. Ligang Yang, a co-investigator on this study and Director of the STD Clinical Quality Control Program at the GDCDC. In his role as director he maintains regular contact with administrators of all eligible health facilities in Guangdong province in order to monitor clinical practice standards, arrange provider trainings, and address issues of clinical service delivery. In the event that Dr. Yang become unable to perform his duties, Dr. Yang Bin, the China site-PI for this grant and director of the entire GDCDC will assume his responsibilities. Given the burden of work for a single person, verbal confirmation procedures will be conducted over the phone or in person only if and when convenient. The script used for verbal confirmation procedures can be found in the document titled "Script for Facility-level Verbal Confirmation." Conversations with facility directors will be documented in a formal

log maintained by Dr. Ligang Yang with support from study staff and will document the dates and times of calls, a checklist of minimally required

Upon receipt of verbal confirmation from facility directors is confirmed, formal consent procedures will begin among the subset of facilities from which confirmation was obtained. Using the provider contact information obtained during verbal confirmation procedures, study staff will approach providers for individual-level consent. In both control and treatment facilities study staff will explain the purpose of the study (which will be described as a generic "healthcare services survey"). They will also ask for consent to administer a face-to-face survey on demographics, professional rank, training history, and attitudes regarding specific medical procedures, as well as to receive an SP visits at some point in the next six months. According to the modified Zelen design, we will then seek consent only from providers in the treatment facilities to take part in the study intervention, a hybrid professional skills building workshop. Control arm participants will be aware that they are part of an observational study but not that they are in the control arm of an intervention study. Our justification for the Zelen design is to avoid artificially inducing changes to the standards of medical care in facilities randomization to the control arm, a common consequence in RCTs to evaluate population based services.[38] Providers will be reminded their participation is entirely voluntary and that refusal to take part in any study activities will not impact their job security, salary, or any other aspect of their professional life. After initial discussion of the study design and procedures, providers will be given time to ask questions and if desired, to take the consent form home with them to have more time to make a final decision around study participation. Individual-level provider encounters will be conducted in person during which consent will be obtained. Consent procedures will entail study staff providing a print version of the consent on a study tablet for participants to read. They will also orally confirm relevant information including details on study scope, participant activities, duration of study, and risks and benefits. In light of preferences expressed by community members who wish to take part in the study but do not wish to sign their own names, we have sought a waiver of written consent. The consent form will include a statement that reads, "by completing this survey you are consenting to be in this study." Participants who proceed with the survey will in this way be providing an alternative documentation of consent. Note that all verbal confirmation and consent procedures (both verbal and written aspects) will be conducted in participants' native language of Mandarin Chinese. Both English and Chinese versions of the consent forms have been prepared for the purposes of ethical review in both the US (University of Minnesota) and China (the GDCDC).

22.2 *Waiver or Alteration of Consent Process:*

N/A

22.3 *Waiver of Written/Signed Documentation of Consent:*

Following early experiences with recruitment and consent, in January 2021, our team formally requested a waiver of written/signed documentation of consent. Our current consent procedures require a digital finger-drawn signature via tablet. The primary justification for this waiver request is due to the fact that a number of otherwise eligible participants have declined to take part in this study due to their reluctance to sign the consent form with their own names. These individuals indicated that they would have otherwise willingly taken part in the study.

We have reviewed the criteria for a waiver of written/signed documentation (From HRP-411) of consent and meet the following:

- The research is not FDA regulated.
- The written script of the information is to be provided both orally and for inspection and review by the participant using the study tablet used to administer the survey questionnaire. Each participant will be offered a printed copy of written information describing the research for their own keeping. They will not be required to accept a form.
- The research presents no more than minimal risk to participants.
- The research does not involve newborn dried bloodspots.
- As detailed in Sections 12.1 and 18.1, study staff will maintain records of providers' names to ensure that unannounced clinic visits do not take place with non-consenting providers. This is the only document that could link a participant with the research. Section 18.1 details the data security measures that will be taken to safeguard this information.
- We have an appropriate alternative method of documenting that consent was obtained. The consent form will include a statement that reads, "by completing this survey you are consenting to be in this study." Participants who proceed with the survey will in this way be providing an alternative documentation of consent.

22.4 *Non-English Speaking Participants:*

All field activities will be conducted in China. As such, enrollment and consent will be conducted in Mandarin Chinese, which is the native language of all potential participants.

22.5 *Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age):*

N/A

22.6 *Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent:*

N/A

22.7 *Adults Unable to Consent:*

- Permission: N/A
- Assent: N/A

23.0 Setting

23.1 *Research Sites:*

All research activities involving human subjects have been and will continue to be conducted in Guangzhou, China in collaboration with the Guangdong STD Control Center (GDCDC). The protocol for the proposed research will be reviewed and monitored by the GDCDC (FWA number 00004801). All study staff have undergone training about human subjects and the study IRB protocol. The two phases of research have been and will continue to be overseen by study staff at the GDCDC. Key personnel oversee study staff in their primary responsibilities of engagement, recruitment, and consent procedures for all study participants.

23.2 *International Research:*

Our team of investigators is evenly divided between local employees of the GDCDC and US-based investigators. The US based investigators including the two co-PIs collectively have decades of experience living, working, and conducting field research in China. They are all fluent in Mandarin Chinese and have fostered years long partnership with local researchers. Conversely researchers at the GDCDC have long international research experience and have administered and co-led multiple NIH funded studies on topics including HIV prevention, MSM heath, and syphilis microbiology.

This study seeks to improve clinical behaviors of providers working DV clinics through job training. Such trainings are common in many clinical settings in China and so the risks associated with participation in this research are considered minimal, even in light of the local customs and norms. This study will take place locally and in a fully Chinese language environment, absolving us for the need for a local participant advocate.

All non-Chinese researchers including students traveling to the study site in Guangzhou, China, will register their travel with their respective Travel Advisory Groups (e.g. for University of Minnesota, with the International Travel Risk Assessment and Advisory Committee).

23.3 *Community Based Participatory Research:*

The goal of this research is to reduce stigmatizing or discriminatory treatment of PLWH or MSM in clinical settings in China where this problem has been extensively documented. Participation and input from the PLWH and MSM communities is critical to the success of our research. To this end we formed a CABs of MSM to ensure that study procedures including the development of the SP training program, the stigma reduction intervention, and the overall study design is conducted in alignment with the values of these communities. The relationship between our study team and the community is supported by a long-standing partnership between investigators at the University of Minnesota, University of North Carolina, the GDCDC, and the Zhitong LGBT Center. These groups have collaborated on numerous projects to address sexual health disparities in this community and to remove barriers to healthcare access. The joint establishment of a “gay-friendly clinic” by GDCDC and Zhitong is the best example of a mutually beneficial relationship which we hope will continue to motivate the CBPR elements of this research.

We also formed a CAB of providers to similarly help us with our study design and implementation. Most stigma reduction programs to date rely on theoretical models to design interventions, which overlooks the opportunity to consult those closest to the problem: providers themselves. Past research has suggested that stigmatizing behavior is rarely driven by disgust or hatred but rather by ignorance, fear, and discomfort. By correctly identifying these drivers, our CAB members can help us build a more appropriate, specific, and ultimately effective intervention to reduce stigma.

24.0 Multi-Site Research

N/A

25.0 Resources Available

25.1 *Resources Available:*

We seek to recruit study facilities out of a possible 46 candidate facilities. Given our success in recruiting 10 clinics in the course of one week during our pilot activities we are confident that recruitment procedures are feasible and unlikely to take longer than one month. Though not considered participants, SP recruitment procedures are also anticipated to encounter few obstacles. In the course of pilot work for this project, the two co-PIs and staff at the Zhitong LGBT Center with whom we are partnering encountered high levels of community interest in the project and 4 SPs were recruited in the course of 2 days. The Zhitong LGBT Center maintains a corps of >200 in-person volunteers and with several hundred more MSM through online engagement. In the unlikely event that we face issues with recruitment we have allocated discretionary funds to take out an ad on a two popular web portals for MSM, www.danlan.org and the partner seeking app, BlueD

Study activities have been and will continue to be based out of the local research site, the Guangdong Center for STD Control & Prevention (GDCDC). Co-PI Dr. Kumi Smith has maintained an active collaboration with the GDCDC for 5 years and is provided access to desk space, internet connectivity, access to printers, and basic office supplies while there. These same resources have been and will continue to extended to the other US-based investigators.

Zhitong maintains an active hotline to provide psychosocial support to members of the LGBT community. Study participants experiencing emotional distress as a result of participating in our research activities have been and will continue to be referred to a trained Zhitong counselor.

Members of our study team have been and will continue to meet on a weekly basis (in person or via conference call when members are in remote locations) to discuss research procedures, any issues arising in the course of research, and to discuss any anticipated activities that may require an amendment to the IRB. Any future study team members recruited to join this project will be onboarded by the study PI (Dr. Smith) to inform them of study protocol and their duties and responsibilities.

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