

HIV Prevention Trials Network

CLARIFICATION MEMO #02 TO:

HPTN 071a - Stigma Ancillary Study

THE ROLE OF HIV-RELATED STIGMA IN THE DELIVERY OF UNIVERSAL TEST AND TREATMENT FOR HIV PREVENTION

Version 1.0 / 06 January 2014

Date of Clarification Memorandum: 14 May 2015

The items clarified in this Clarification Memorandum (CM) have been approved by the DAIDS Medical Officer and are to be implemented immediately upon issuance. IRB/EC approval of this CM is not required by the sponsor; however, investigators may submit the CM to the IRB/EC overseeing the study at their site for information. This CM is official HPTN 071a (Stigma Ancillary Study) documentation and is effective immediately.

This CM and all related IRB/EC correspondence must be retained in the site regulatory file and in other pertinent files. Protocol registration approval is not required by DAIDS for CMs.

If the full HPTN 071a protocol is amended in the future, the changes in this CM will be incorporated into the next version of the protocol.

Summary of Revisions and Rationale

This CM serves to:

- 1) Replace the acronym CARES (Clients at Risk of Exclusion) with “Key Populations”
- 2) Update the protocol team roster
- 3) Clarify the visit schedule and study timelines
- 4) Add some operational details regarding electronic data capture procedures
- 5) Provide a more accurate estimate of the sample size
- 6) Correct minor grammatical and typographical errors

Changes in the protocol are summarized below by section. Added text appears in **bold face** and deleted text appears with a ~~strike through~~.

List of Abbreviations and Acronyms

CARES ————— Clients at Risk of Exclusion

Protocol Team Roster

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Section 1.1 Background

The study gives special attention to interactions between health workers and potential clients of HIV-related services, including ~~some we describe as “clients at risk of exclusion”~~ (CAREs **key populations**), who may experience particular barriers to accessing UTT and combination prevention interventions, including women engaged in exchanging sex for money or resources and men who have sex with men.

Section 2.1 Objectives

- (4) Contextualise findings through longitudinal qualitative and participatory research with a focus on understanding interactions between CHiPs, health facility staff and potential clients of HIV-related services, especially ~~clients at risk of exclusion (CAREs)~~ **key populations**.

Section 2.2 Study Design

Interviews with cohort members will occur at baseline (during the first year of PopART delivery, or upon entry to the cohort), in the second year of PopART delivery, and ~~after three years (during the final year of the trial)~~. Exit interviews will be undertaken with consenting individuals who leave employment with the CHiPS or relevant health facility **if feasible**.

Section 2.3 Timing and Deployment of Research Components

~~2.3 Timing and Deployment of Research Components~~

(Table removed)

Year	2013			2014				2015				2016				2017			
Quarter	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3
Key Dates																			
Date																			Current End Date: 30 Sept
Set up																			
Contracts in place																			
Protocol Development																			
Protocol and ethical reviews																			
SOP development for enumeration																			
SOP development for survey implementation																			
Questionnaire design (programming/revision)																			
Field work																			
Training #As to do Data Collection																			
SOP review/revision																			
CHI PaHS Cohort (Zambia)																			
CHI PaHS Cohort (South Africa)																			
Final data management and archiving processes																			
Qualitative and Participatory Research																			
Documenting stigma reduction																			
HMW interviews																			
New Populations qual interviews																			
Strengthen assessments in HPTN071 Fieldwork																			
Design PC Data collection tools																			
Population Cohort																			
QCC																			
QCC																			
QCC																			
Analysis																			
CHI PaHS Cohort																			
Qualitative analysis																			
Final and integrated analysis																			
Data management & archival meeting, Cape Town																			
Data analysis workshop, London																			
AS 2016 Meeting reporting																			
Other Scientific Work																			
Preliminary Analysis of PC Data on stigma questions																			
Analysis of 500 stigma-related data																			
Multi-country DHS data on change in stigma overtime																			
Chief of Research led data association of how stigma measures with HIV testing behavior																			
Chief of Study Design Paper																			
Potential Travel																			
Supervising/Training #As																			
Site visits during data collection																			
Annual Meeting																			
Analysis Meeting																			
AS Meeting - site specific meeting																			

Completed Work

Section 3.0 Study Interventions

A nine day ~~tr~~Training for CHiPs will include some specific training on addressing stigma within families and stigma associated with condom use and ART adherence and will ask CHiPs to reflect on their own stigma experiences.

Section 5.1.3 Selection of Study Participants

Interviews with health facility managers and a document review process will enumerate health workers and screen against the inclusion criteria in each facility.

Section 5.1.4 Negotiating Access to Potential Participants

In each country, the study coordinator will liaise with the intervention coordinator(s) to draft a schedule for data collection. ~~The CHiPs data collection schedule is anticipated to run for three months from the start of the study.~~

~~Data collection with HFS will run for approximately four months in each year. The schedule should minimise impact on HFS routine work.~~

Section 5.1.5 Data Collection

A data collection tool will be designed for facilitated self-delivery using PDAs [see Section 5.1.6 – Data Management]. HFS and CHiPs will receive similar questionnaires, however, some questions may be limited to one group or the other, given the different environments in which they work. These PDAs will be password protected and will only be available to authorized staff. Electronically kept personal identifiers will be stored in separate datasets with password protection only accessible for designated staff (for computers and servers).

We anticipate that in some cases, participants might prefer to answer a paper version of the questionnaire. In such cases, paper questionnaires will be available. Research Assistants will be on hand to answer any questions and ensure confidentiality while the participant is completing the survey. The responses will later be entered by a member of the research staff. Paper questionnaires will not include participants' names. They will be signed and dated by the Research Assistant administering the questionnaire and will be stored in a locked cabinet, only accessible to study staff.

In some circumstances, if a participant is unable to use the EDC (i.e. if a participant is illiterate) or if a participant is not comfortable doing the self-administered survey as programmed on the EDC, a Research Assistant may administer the questionnaire to the participant, and fill in the information on the EDC.

At baseline, the tool will cover a range of topics including the following:

Further, participants will be encouraged to take as long as they need to answer questions honestly and to ask for clarification from the field staff at every point at which this is helpful.

~~In special circumstances, if a participant is unable to use the EDC (i.e. if a participant is illiterate, or are not comfortable doing the self-administered survey as programmed on the electronic data collection devices), a Research Assistant may administer the questionnaire to the participant, and fill in the information on the EDC.~~

Section 5.1.7 Retention

Any member of the cohort who leaves their role in delivering the UTT intervention, thereby no longer meeting the inclusion criteria, will be censored. Exit interviews will be conducted close to the date of censoring **if feasible**.

Section 6.1 Sample Size for Cohort Study

We will include all CHIPS workers and all health facility staff in all 21 study clusters that meet the inclusion criteria described in Section 5.1.1 in the study. **At baseline, we estimate that over 2000 individuals will be eligible to participate.** ~~We therefore expect to include a total of 2000-1240 individuals in the study.~~

We expect the total number of CHiPs workers across all communities to be approximately 736, with some variability by cluster (~~expected~~ **estimated** range 40-80) reflecting variation in the size of the clusters. We expect the total number of HFS to be approximately ~~504~~ **1300**, reflecting an average of ~~6024~~ individuals per cluster again with some variability linked to cluster size (~~expected~~ **estimated** range 15-40).

Section 6.1.1 Justification of Sample Size

We considered both statistical and pragmatic / feasibility issues in deciding on sample size. The primary justification for including ~~1240 individuals, that is all individuals meeting the inclusion criteria;~~ was as follows:

- The number of clusters was pre-set by the HPTN071 study (n=21), ~~as was the maximum possible sample size of both CHiPs (expected n=736) and HFS (expected n=504)~~

Section 6.2.1 Objective 1

Using data on the **estimated** dates on which individual cohort members leave active service following recruitment to the cohort and are replaced by other individuals, we will describe the turnover and rates of attrition of health workers and how this varies by key sociodemographic characteristics, including by type of participant, country, cluster and over time.

Section 6.3 Objective 4: Analysis of Qualitative Data

Key areas of analytic focus will include

- Which factors inhibit and/or facilitate HIV related stigma at community level?
- How are events relevant to stigma contextualised in terms of HIV services and community life?
- What is the ‘information to action cascade’ from the intention of an event, what participants understood of this, how this understanding was internalised, and what action they took subsequently?
- How are members of **CAREs key populations** and their interests represented by, and represented in events relevant to stigma?
- How is stigma embodied in the clinic space? How is it challenged?
- How is stigma embodied in HIV clinic practice? How is it challenged?
- How does stigma experienced by CHiPs and HFS who are themselves living with HIV impact on stigma?
- How is the extension of health services into the community impacting on the clinic/community space and the experiences of people ‘wearing both hats’?
- How do CHiPs and HFS engage with members of **CAREs key populations** in their professional and private capacities?
- How do members of **CAREs key populations** experience the stigma in their relationships with CHiPs and HFS and as clients of this system?
- How do members of **CAREs’ key populations** experiences of HIV prevention, treatment and care relate to (reinforce, redefine, or escape) their perceived social position? How does it manifest in their movement in the clinic and community spaces?

Section 8.2 Risks

We will minimize the risks identified above through:

- Robust and transparent procedures for fully-informed consent
- Maintaining **as much confidentiality as possible** of individual responses at all stages

Section 8.3.1 Confidentiality

This starts with the approach used for data collection. Participants will be trained in the use an electronic data collection device (EDC) to enter responses to questions in a “self-interview”. Consequently participants will not need to share their responses to any questions with any other individual **when using the EDC**. EDC data collection will not be visible at either the point of entry or prior to data upload to those facilitating self-interview sessions, **except in some circumstances described below**.

In some cases, participants might prefer to answer a paper version of the questionnaire. In such cases, paper questionnaires will be available. Research Assistants will be on hand to answer any questions and ensure confidentiality while the participant is completing the survey. The responses will later be entered by a member of research staff. Paper questionnaires will not include participants' names. They will be signed and dated by the Research Assistant administering the questionnaire and will be stored in a locked cabinet, only accessible to study staff.

In other circumstances, if a participant is unable to use the EDC (i.e. if a participant is illiterate) or if a participant is not comfortable doing the self-administered survey as programmed on the EDC, a Research Assistant may administer the questionnaire to the participant, and fill in the information on the EDC.

Personal identifiers will appear on paper or electronically on appointment books, consent forms, log books, follow up lists and other listings. These listings will **not NOT** include any (sensitive) study information. A unique study number will be used to link personal identifiers to study information.