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CAPRISA 106 Tenofovir Gel Social and Health Systems Research Study

End of Study/Lessons learned report

CAPRISA

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Introduction

The CAPRISA 106 Tenofovir Gel Social and Health Systems Research Study was an ancillary study to the CAPRISA 008 study, a two-arm, open-label randomized controlled trial assessing the implementation effectiveness and safety of 1% tenofovir (TFV) gel provision through family planning (FP) services in KwaZulu-Natal, South Africa. The CAPRISA 008 control arm was conducted in CAPRISA research clinics with monthly provision and monitoring of TFV gel, while the intervention arm was conducted at neighboring FP clinics with 2-3 monthly provision and monitoring of TFV gel, combined with a health systems strengthening/quality improvement (HSS/QI) approach to promote reliable service delivery.

With implementation of the CAPRISA 008 open label TFV gel study underway, an opportunity existed to conduct ancillary research among women using TFV gel in a non-placebo-controlled study. The provision of open-label TFV gel removes a key element of uncertainty in women's decision-making about product use and also provides a unique opportunity to conduct formative health systems research on TFV gel provision in a family planning context, closer to that found in real-world settings.

This report highlights the lessons learnt and challenges encountered during the course of this project.

Study Design and Methodology

Purpose and Objectives

The purpose of this study was to describe social and health systems experience with TFV gel in the context of CAPRISA 008, in order to inform the design of potential future TFV gel demonstration projects.

The objectives of the study were:

1. To explore the interface between social context and user experience with open label TFV gel use, specifically:
 - a) The social acceptability of coitally-related use of TFV gel among women and men;
 - b) The influence of gender dynamics on gel use disclosure, adherence, and continuation; and
 - c) The social barriers and facilitators to compliance with medical requirements associated with TFV gel use.
2. To explore the CAPRISA 008 experience with implementing the HSS/QI approach for integrated FP/TFV gel service provision, specifically:
 - a) To assess fidelity of the HSS/QI approach applied;
 - b) To describe perceptions of the HSS/QI approach, implementation process, and service delivery experience among CAPRISA 008 providers, research staff and participants;
 - c) To describe the resources used for, and estimate the cost of, the HSS/QI approach for FP/TFV gel service provision; and
 - d) To describe changes in service delivery performance over time.

Study Design

This was a descriptive, exploratory study using a mixed methods design (qualitative and quantitative data collection and analysis).

For **objective 1** (exploring the social context and TFV gel user experience) data collection methods centered on use of focus group discussions (FGDs) and in-depth interviews (IDIs) conducted in real time with implementation of the CAPRISA 008 trial. We used purposive sampling to identify women who disclosed TFV gel use to their partners and those who do not, at each site (urban, rural) and in each CAPRISA 008 study facility (intervention and control). We also sought to recruit the male partners to whom women have disclosed as well as men from the community who are not partners of CAPRISA 008 study participants.

For **objective 2** (exploring the HSS/QI and integrated FP/TFV gel service provision experience) data collection included IDIs and document review and abstraction at CAPRISA 008 clinics. Convenience sampling was used to recruit CAPRISA 008 providers, research staff, and participants. Documentation of the HSS/QI process and FP/TFV gel service provision were reviewed and data abstracted to evaluate implementation fidelity, describe impacts on service delivery over time, and assess costs associated with implementation.

Target Population, Inclusion Criteria and Data Collection Equipment

Target Population

The study involved the systematic collection of data from KwaZulu-Natal, South Africa, and included women and men aged 18 years and older in the Vulindlela subdistrict and eThekweni municipality where the CAPRISA 008 study was underway.

Research participants included:

- Women participating in the CAPRISA 008 study
- Male partners of women participating in the CAPRISA 008 study
- Men residing in the communities where the CAPRISA 008 study is being implemented
- CAPRISA 008 providers and research staff

Inclusion Criteria

1. Women participating in the CAPRISA 008 study and not currently on product hold
 - Age 18 years and older who are sexually active, HIV-uninfected, non-pregnant women at the time of enrollment into CAPRISA 008
2. Male partners of women participating in the CAPRISA 008 study
 - Age 18 years and older male partner of a CAPRISA 008 participant to whom the CAPRISA 008 participant has disclosed (a) that she is participating in the CAPRISA 008 study, (b) that as a participant she is using tenofovir gel, and (c) that tenofovir gel is an ARV product designed to reduce her risk of HIV infection
3. Men residing in the communities where the CAPRISA 008 study is being implemented
 - Age 18 years and older who are demographically similar to the CAPRISA 008 male partners described above
4. CAPRISA 008 providers and research staff
 - Age 18 years and older male or female providers and research staff who are (a) providing direct patient care, including FP and/or TFV gel provision, and/or (b) play an integral role in CAPRISA 008 research, QI and service operations

Data Collection Equipment

The following were the types of equipment used for study administration

Table 1. Study Equipment

Equipment	Number	Purpose
Panasonic Digital Recorder	07	To record the articulated voices of the participants verbatim. This enabled the team to 'capture' the entire conversation and have a detailed record of the IDI/FGD in the participant's own words. Furthermore, one was able to listen carefully and to follow up or probe interesting avenues without the need to write down everything that was stated by the participant.
Science II foot pedals	07	To make the transcribing process more efficient since there is no need to use manual controls from the computer or recorder.
F4 software: Audiotranskription.de	05	This transcription software made the process of transcribing from the audio faster and easier.
Logitech H150/ Logitek headset	13	To maintain confidentiality when listening to audios during transcription. These were also used during skype meetings.

Lifebook S752 Notebook	10	Used for transfer and storage of audios/ data. Used during transcription and translation as well as other administrative and project duties such as report writing.
Voyager Digital Recorder Bags	04	To store recorders and prevent them from getting damaged.

Study Sites

The CAPRISA eThekweni Site

The CAPRISA eThekweni Site is adjacent and attached to the Prince Cyril Zulu Communicable Disease Center a Primary Health Care Clinic dedicated to treatment of TB and sexually transmitted infections (STI). This facility is conveniently located in central Durban in the transport hub for public commuters by rail, bus or minibus taxis. The CAPRISA eThekweni site comprises two sections, a Treatment Clinic for HIV-TB co-infected patients and a Prevention Clinic with a high risk population of STI clients.

The CAPRISA Vulindlela Site

Vulindlela is a predominantly Zulu-speaking rural community of about 400,000 people located 150 kilometers west of Durban. The district has 8 Primary Health Care clinics where nurses provide comprehensive primary care, including family planning services, voluntary HIV counseling and testing, sexually transmitted infection treatment, antenatal care, treatment of opportunistic infections and minor ailments. They are linked by ambulance to the regional referral hospitals, Grey's Hospital (about 30 minutes away), and Edendale Hospital (about 20 minutes away). The CAPRISA Vulindlela Clinical Research Site was established by invitation from the two traditional chiefs, Nkosi Sondelani Zondi and Nkosi Nsikayezwe Zondi. The partnership between the CAPRISA researchers, community organizations, community leadership and health service providers in this district is now well established based on significant joint efforts to deal with the unfolding AIDS epidemic in Vulindlela.

Challenges with study sites and any action taken by the team to address those challenges

- Challenge:* Initially, there had been some difficulty in ensuring internet connectivity particularly for staff at the rural VL site. The office in which the staff were based did not have internet cables and thus they relied on the use of the wireless network.

Action: Internet cables were installed in the CAP 106 office in August 2013 which improved connectivity. Further, a 3G modem was also procured to augment connectivity options.
- Challenge:* There were times where sites experienced network connection problems. The shared space was thus inaccessible for the site staff.

Action: External hard-drives were purchased and the shared drive was backed up weekly. Thus in cases of network problems, staff were still able to continue with data processing activities by using the backups of the shared drive.
- Challenge:* At the beginning of the study there was no landline phone that was located in the CAP 106 office at the VL site.

Action: Staff were assigned a cordless phone in a neighbouring office to use. Skype was also installed on all CAP 106 staff computers. Telephone points were installed in the CAP 106 office in August 2013 and a landline telephone was assigned.
- Challenge:* There was no designated driver or vehicle at the ETK site for recruitment for community men.

Action: A vehicle was hired for recruitment activity for community men.
- Challenge:* There was an issue of space for interviewing at the ETK site as there was only 6 counselling rooms and 1 community room servicing multiple projects. Certain rooms were assigned to certain projects and could not be used.

Participant Accrual

The CAPRISA 106 study had an accrual target of approximately 450 enrolled participants over an anticipated period of approximately 6 to 12 months. The CAPRISA 106 study recruited and enrolled from 4 participant groups:

1. Women Participating in the CAPRISA 008 Study

1.1 Recruitment of women for disclosed and non-disclosed events

Potential participants were identified by the study coordinators at each site. CAPRISA 106 study coordinators requested from the CAP 008 administrators weekly schedulers, which contained the dates participants were expected and the visit they were due for that week. From this subset of participants, CAPRISA 106 study coordinators identified those who were currently not on product hold in CAPRISA 008 and have been in the study for at least 6 months. The CAP 106 study co-ordinator would then populate names of the eligible participants onto a list along with their next scheduled clinic visit. This list was shared with the CAPRISA 106 Research Assistant who would be responsible for completing the last column with participants that have already been recruited. He/she then made copies of this and gave to the CAP 008 administrators; in order to assist the CAPRISA 106 Research Team to identify the potential participant when they arrived at the clinic.

Once a participant from this list presented to the site, the CAPRISA 008 Research Administrator informed the CAPRISA 106 Study Coordinator and Research Team. The potential participant continued with their scheduled CAPRISA 008 study visit. During appointment waiting periods the CAPRISA 106 Research Team made efforts to inform and recruit these potential participants utilizing the General Information for Potential Participants Sheet and the CAPRISA 106 Recruitment Script for Women Participants. An Interest Follow-Up Script was used if there were time constraints or if the CAPRISA 106 Research Team member was not available and the recruitment effort was being conducted by other designated staff such as the Community Liaison Officer. In the instance of time constraints, after the potential participant had been told about the study by the CAP 106 Research Assistant using the Interest Follow-Up Script, the Recruitment Form was completed regardless if they decided to schedule an interview. A Contact Form was completed if the potential participant scheduled an interview during recruitment.

During recruitment disclosure of tenofovir gel use was assessed. For the purpose of this study, “disclosure” meant the CAPRISA 008 participant had informed her partner all of the following:

- She was currently using a gel as part of a research study
- She was using the gel to prevent HIV infection
- The gel contains an ARV

In cases where a participant failed to disclose all three components (partial discloser), the research assistant would ask the participant if she would be willing to disclose the remaining component to her partner. If the participant agreed, the research assistant would re-contact the participant telephonically to check if she has disclosed the remaining component and then classify her accordingly. If the participant did not wish to disclose the remaining component to her partner, she would be classified as a non-disclosed participant.

1.2 Recruitment of Woman for Motivations FGD’s

The CAPRISA statistical centre provided the study coordinator with a list of CAP 008 participants who fitted into one of three adherence categories (low, medium or high) based on data from CAP 004. Each category was assigned a coded nominal adherence name (e.g., fruit) by the study coordinator to protect adherence information. The association of the adherence code to a particular adherence group remained confidential – known only by the study coordinator and the site PI; therefore, all other CAP 106 staff were blinded to the adherence status of the participants. Site Study Coordinators created a list of potential

CAP106 PINs for each adherence group. RAs used this list to call potential participants directly to assess their interest in participating in the Motivations FGD. If the RA was unable to contact this participant they attempted to recruit participants in person when they arrived at the clinic for their scheduled CAP008 visit. To facilitate this, the study coordinator received that weekly scheduler from the CAP 008 administrator and identified these participants and informed a CAP106 RA that the participant has arrived. This adherence group reflected in the archival numbers of the FGD.

On the day of the event, RAs verified the list of eligible PINs for the specific FGD scheduled for that day. If a potential participant arrived for the FGD and their PIN was not on the list of eligible PINs for that FGD the study coordinator, or designee would attempt to schedule the individual to participate in another FGD if needed.

1.3 Recruitment of Women for Support FGD's

Women already recruited by CAP106 staff were re-contacted by appropriate study staff to assess their interest in participating in the Support FGD. Women who expressed interest in participating in the FGD were scheduled to arrive at the FGD venue on the scheduled date for the discussion and brought proof of their identity. CAP106 staff recorded their attempts at recruiting participants for this FGD just as they did in earlier FGD recruitment activities.

On the day of the event, RAs verified the list of eligible PINs for the specific FGD scheduled for that day. If a potential participant arrived for the FGD and their PIN was not on the list of eligible PINs for that FGD the study coordinator, or designee would attempt to schedule the individual to participate in another FGD if needed.

2. Male Partners of Women Participating in the CAPRISA 008 Study

Male partners were only recruited through their partner who was participating in the CAPRISA 008 study. Only male partners to whom gel use had been disclosed by their female partners were recruited for CAPRISA 106.

Women who disclosed their tenofovir gel use as per disclosure criteria defined by this study to their partner were asked at the end of their CAPRISA 106 interview or FGD if they would be willing to refer their partner to the study. If the participant was willing to put her disclosed partner(s) into contact with the CAPRISA 106 Research Team, she was given a Recruitment Card, with her screening number and information on how to contact the CAPRISA 106 Research Team. When the partner(s) came to the clinic or sent a "call-back" message they used their referring partner's screening number to identify them to the CAPRISA 106 Research Team. This number verified that he was referred by his partner and that he did not hear about his potential to participate independent from her.

Men were also screened as part of the enrolment procedures; specific screening questions for male partners were incorporated in the text of the Recruitment Script for Male Partners of 008 Participants. The Recruitment Script for Male Partners of 008 Participants asked potential participants if they were interested in participating in a Male Partner IDI and/or a Male Partner FGD. After the person indicated the activity (or activities) in which they were interested in participating, the guidelines for recruiting for specific activities were followed. Male partners who were interested in participating in both an IDI and FGD were recruited to participate in both activities depending on accrual targets of the study at the time of recruitment.

Once the partner got in contact with the Research Team (either by phone or in person) he would be assigned a unique Screening Number of his own – this was linked to his referring partner's PIN in the Recruitment Form and Data Collection Log. The potential participant was informed of the study utilizing the General Information for Potential Participants Sheet and the Recruitment Script for Male Partners of 008 Participants. After the potential participant had been told about the study, the Recruitment Form was completed. A Contact Form was completed if the potential participant scheduled an interview during recruitment.

3. Men Residing in Communities where the CAPRISA 008 Study was being implemented, who were not partners of CAPRISA 008 participants

This group was recruited with the assistance of local study staff and community liaisons at CAPVL and CAPTK. As per eligibility requirements this group of participants were demographically similar to male partners of CAPRISA 008 participants and were recruited from the communities where the CAPRISA 008 study was being implemented. To minimize the possibility of recruiting a CAPRISA 008 sexual partner who has not been disclosed to by a participant – or other men who happen to know CAPRISA 008 participants but may not be fully aware of the specifics of the trial – CAPVL attempted to recruit men residing within the same municipality but beyond a 20km radius from the CAPRISA 008 catchment area. CAPTK tried to sample in densely populated areas in Durban where CAPRISA 008 participants do not reside.

Details of the recruitment strategy for this group were developed in on-going consultation with the Community Advisory Board and CAPRISA Community Liaison Officers. The recruitment strategy included face-to-face discussions, distributing recruitment flyers or posting them at social settings often frequented by men such as bars, clubs, car-washes, barber shops or sporting venues. Men who responded to these recruitment activities were informed about the CAPRISA 008 study and asked whether they knew anyone participating in the study. After the participant had been told about the study the Recruitment Form and Contact Form were completed.

4. CAPRISA 008 Providers and Research Staff

CAPRISA 106 Research Team informed CAPRISA 008 Providers and Research Staff of the study and the purpose of the interview, that participation was completely voluntary, and that refusal would not affect their position in any way. The CAPRISA 106 Research Team met individually with CAPRISA 008 staff to try to enrol potential participants in the interviews. The CAPRISA 106 Research Team utilized the Recruitment Script for CAPRISA 008 Providers and Research Staff. If the provider or research staff member agreed to participate, the Recruitment Form was filled out. Potential participants were given the option to interview away from the research clinic. A Contact Form was filled out if the participant chose to be interviewed at a later time/date.

Table 2. Participant Accrual

Participant Type	# Recruited Per Site	Study Site
CAP008 disclosed participants (IDI)	25	FPVL
	17	CAPVL
	06	FPTK
	11	CAPTK
CAP008 disclosed participants (FGD)	09	FPVL
	11	CAPVL
	01	FPTK
	06	CAPTK
CAP008 disclosed participants (IDI & FGD)	18	FPVL
	34	CAPVL
	05	FPTK
	14	CAPTK
CAP008 non-disclosed participants (IDI)	17	FPVL
	06	CAPVL
	02	FPTK
	04	CAPTK
CAP008 non-disclosed participants (FGD)	05	FPVL
	08	CAPVL
	04	FPTK
	06	CAPTK

CAP008 non-disclosed participants (IDI & FGD)	11	FPVL
	15	CAPVL
	11	FPTK
	04	CAPTK
CAP008 Male partner (IDI)	04	FPVL
	04	CAPVL
	01	FPTK
	04	CAPTK
CAP008 Male partner (FGD)	00	FPVL
	01	CAPVL
	00	FPTK
	00	CAPTK
CAP008 Male partner (IDI & FGD)	00	FPVL
	00	CAPVL
	00	FPTK
	00	CAPTK
CAP008 provider/research staff (IDI)	05	FPVL
	12	CAPVL
	01	FPTK
	10	CAPTK
CAP008 Participants (clinic experience IDIs)	06	FPVL
	01	CAPVL
	10	FPTK
	06	CAPTK
CAP008 Participants (support FGDs)	16	VL
	17	TK
CAP008 Participants (motivations FGDs)	45	VL
	24	TK
CAP008 Participants (motivations & support FGDs)	5	VL
	12	TK
Community men (FGDs)	32	VL
	23	TK
Total # Participants Recruited	489	

Table 3. Participant Enrolment

Participant Type	# Enrolled Per Site	Study Site
CAP008 disclosed participants (IDI)	08	FPVL
	10	CAPVL
	08	FPTK
	13	CAPTK
CAP008 disclosed participants (FGD)	06	FPVL
	07	CAPVL
	04	FPTK
	14	CAPTK
CAP008 non-disclosed participants (IDI)	06	FPVL
	06	CAPVL
	06	FPTK
	07	CAPTK
CAP008 non-disclosed participants (FGD)	07	FPVL
	05	CAPVL

	05	FPTK
	05	CAPTK
CAP008 Male partner (IDI)	04	FPVL
	04	CAPVL
	01	FPTK
	04	CAPTK
CAP008 provider/research staff (IDI)	04	FPVL
	11	CAPVL
	01	FPTK
	08	CAPTK
CAP008 Participants (clinic experience IDIs)	13	FPVL
	11	CAPVL
	08	FPTK
	09	CAPTK
CAP008 Participants (support FGDs)	14	VL
	06	TK
CAP008 Participants (motivations FGDs)	34	VL
	17	TK
Community men (FGD)	21	VL
	20	TK
Total # Participants Enrolled	307	

Challenges with participant accrual/recruitment and any action taken by the team to address those challenges

- Challenge:* At both sites difficulties were experienced in recruiting non-disclosed participants.
Action: It was agreed by the CAP 106 local PI and CAP 008 Co-PI that the CAP 008 administrators would check the eligibility including disclosure status and conduct telephonic interest to follow ups with any eligible participants. Those participants who were interested were then referred to the 106 staff for recruitment.
- Challenge:* At the VL site PIN 302 was recruited twice in error. It was agreed that she be assigned her first screening number as her PIN number and that the incorrect screening number is not removed from the data collection log.
Action: The research assistant (RA 01) was informed that she:

 - Must follow the previously prescribed process and ensure that all previously recruited participants are removed from the list of potential participants circulated by the Study co-ordinator weekly.
 - Prior to proceeding with the recruitment script, she asks participants whether they have been recruited already.
- Challenge:* At both sites challenges were experienced with partner recruitment and referral.
Action: Majority of men at Vulindlela work away from home and when they were off from work their priority was to spend time with their families so they would not want to spend their time being interviewed. The RAs continued with the follow-up of participants who said they would refer partners. The RAs also communicated to the participants that IDIs can be done on weekends and if available the male RAs were introduced on the phone or in person. The local PI also presented a CAP 106 project update at the CRSG meeting held on the 16th of October. She sought their advice around recruiting male partners for 106 and their suggestions were communicated to the team.

- Challenge:* During recruitment at the VL site one participant was asked how she could be contacted and her response was that she cannot be contacted at all as she does not have a cell or landline number.

Action: The participant was asked further if there were other people that she could be contacted through and she said no. The RA then explained to her why her contact details were needed and important. The participant still didn't give out her contact details and said she can be contacted on her next CAP 008 visit, which the participant provided.
- Challenge:* At the VL site, cases occurred whereby friends or siblings (from CAP 008) of the CAP 106 participant wanted to join CAP 106.

Action: The RAs were encouraged to be careful in communications about study participation to try to explain that not everyone from CAP 008 will be asked to participate in CAP 106. It was highlighted to participants that we are trying to get diverse perspectives and it may be that in some cases one friend or family member is asked to participate and the other is not and that we are sorry if this causes any inconvenience.
- Challenge:* The ETK RAs experienced challenges with recruitment of FP participants due to the fact that FP participants have clinic visits once every 2 or 3 months so this resulted in some participants being missed. During biannual visits participants would spend a lot of time with the nurse and immediately after the visit they would rush off to work and the RAs wouldn't get a chance to recruit them.

Action: A participant tracking list was introduced, which listed the CAP 008 FP participants. The CAP 008 Tracker called the FP participants on the list and assessed their interest in the study. If the participants were interested, with their permission their contact details were given to a CAP106 RA for follow up and recruitment.

Consenting and Data Collection

Informed Consent

All informed consent forms were translated into isiZulu and back-translated to assure accuracy. Prior to administering the enrolment informed consent, each potential participant met individually/privately with a study staff member to establish the potential participant's linguistic preference for the consent process. The enrolment informed consent was in the language of his/her choice: English or IsiZulu. Based on the volunteer's decision, all subsequent study procedures were conducted in the preferred language indicated by the potential participant using the appropriate forms and tools. Study staff explained the study and its associated procedures, risks, and benefits to eligible participants. They then asked an eligible participant to sign an informed consent form if she/he wished to participate. Participants were offered copies of their signed consent forms.

Study staff determined whether the volunteer could read by asking the participant to read a portion of the Informed Consent Form and write at least her/his name. An impartial witness was required for the entire informed consent process for any participant who is illiterate per CAPRISA guidelines for determining appropriate literacy for research consent.

Data collection

All IDIs and FGDs were conducted either in English or in isiZulu per the participant's preference. IDIs lasted up to 2 hours and FGDS lasted up to 2.5 hours. All events were audio recorded when permission was granted by the participant. For FGDs, two study staff were present; one served as the moderator and the other as the note-taker. Between 6 to 10 participants participated in each FGD.

To enhance participant comfort levels, IDIs and FGDs with CAPRISA 008 participants and men were conducted by study staff of the same sex as the participant. Participants were given the option to have the IDI conducted at a mutually agreed upon location in the community including the CAPRISA research

clinics; this included the participant’s home if confidentiality and staff safety could be assured. FGDs took place at recognized community meeting spaces which were easily accessible to study participants, including the CAPRISA research clinics. For IDIs with CAPRISA 008 providers and research staff, age and status-appropriate study staff conducted data collection. For CAPRISA 008 providers and research staff, the interview were conducted in a private area in or near the research clinic as preferred by the interviewee.

Table 4: Data Collection Events

Data Collection Activity	# of Data Collection events Per Site	Study Site
CAP008 disclosed participants IDIs on adherence & continuation	08	FPVL
	10	CAPVL
	08	FPTK
	13	CAPTK
CAP008 non-disclosed participants IDIs on adherence & continuation	06	FPVL
	06	CAPVL
	06	FPTK
	07	CAPTK
Male partner IDIs on adherence & continuation	04	FPVL
	04	CAPVL
	01	FPTK
	04	CAPTK
CAP008 participant IDIs on clinic experience	13	FPVL
	11	CAPVL
	08	FPTK
	09	CAPTK
CAP008 provider/research staff IDIs on experience with HSS/QI and clinic service delivery	04	FPVL
	11	CAPVL
	01	FPTK
	08	CAPTK
CAP008 participant non-discloser FGDs on acceptability & compliance	01	FPVL
	01	CAPVL
	01	FPTK
	01	CAPTK
CAP008 participant discloser FGD on acceptability & compliance	01	FPVL
	01	CAPVL
	01	FPTK
	02	CAPTK
Community men FGD on acceptability & compliance	02	VL
	02	TK
Motivations FGDs	04	VL
	03	TK
Support FGDs	02	VL
	01	TK
HSS QI documents collected	62	VL
	11	TK
	13	Other documents
Total # Data Collection Events	251	

Challenges with consenting and data collection and any action taken by the team to address those challenges

- *Challenge:* At TK site a protocol deviation occurred on 13 August 2013 for PIN 600, whereby a RA carried and used an incorrect informed consent for a CAP 008 disclosed participant IDI. Further, at both sites incidents of participants failing to write their surnames on the informed consent were noted.
Action: With regards to incorrect consent form, the study coordinator informed the staff member of the seriousness of the deviation and how to proceed in the future. A protocol deviation report was submitted to BREC on the 22nd of August 2013. As corrective action for participants who omitted to write their surname, the participants were asked to correct the informed consent at their next 008 clinic visit. A QC step was added for the on-site data collection events, where the study coordinator/designee checked the informed consent documents before the participant was reimbursed. In the cases of off-site IDI's this was not possible but for off-site FGD's the note-taker did a QC on the ICF's prior to re-imburement.
- *Challenge:* Participants and providers expressed concern, especially one's scheduled for the HSS IDIs about having IDIs conducted on site, and asked whether staff could hear what they were saying, they could sometimes see/hear staff walking past while having their IDI.
Action: Offsite venues, close to site were explored and participants were provided with the option of whether they would want to have their IDI on or off site.
- *Challenge:* At the TK site, participants were noted to be more reserved in terms of responses in the HSS participant IDI's.
Action: The RA's were encouraged to emphasize to participants that confidentiality will be maintained and highlight this to them from the informed consent. Also the option of conducting these IDIs off site were provided to participants. An off-site venue was booked for the month of November.
- *Challenge:* At the TK site, a male partner that was interviewed was not a South African citizen and could not speak proper Zulu or English. The male partner opted to do the IDI in Zulu since his Zulu was better than his English. However, the RA had to continually explain the questions in the guide because the Zulu in the guide was at a higher level than his understanding. As a result transcription was going to be challenging.
Action: The RA wrote up expanded notes for this IDI and used the audio to supplement and inform the expanded notes.
- *Challenge:* During the male partner IDIs conducted at both sites it surfaced that though the female partner believed that she had fully disclosed to her partner, the partner did not always know about all 3 components.
Action: It was agreed that following the IDI, the male RAs' called to follow-up with partners to inquire on how things were going. They would thank them for their participation and informed them of the staff member that they could meet to have further questions or concerns addressed.
- *Challenge:* A CAPRISA 106 Research Assistant (RA 01) used the incorrect version of the CAPRISA 008 Participant in-depth interview guide in error for 7 interviews she conducted. The guide she used had the incorrect introductory section on page 1 which the Research Assistant completes. The content of the incorrect version of the guide is the same as the most current version in use. All latest versions of guides are on the shared drive.
Action: The research assistant was informed to ensure that she only uses versions from the shared drive. A note to file was written to explain the error that occurred.

- Challenge:* At the TK site, a participant had been on product for one month after enrollment prior to the initiation of the product hold due to pregnancy. The participant delivered on the 25th of September 2013. During her first post-delivery visit on the 1st of October 2013, she was recruited by CAP 106. Her study visit was split due to there being a faint line on the pregnancy test, and she was advised to come in after 2 weeks to complete the visit at which point she would receive the product. She did not come in and the visit was missed. She then came in for her subsequent visit on the 22nd of October 2013 and product was resumed. A CAP 106 IDI (non-disclosed social) was conducted on the same day.

Action: The PI was informed and the Study co-ordinator was advised that this is not considered as an enrolment violation as when the participant was enrolled into CAPRISA 106 she was no longer on study product hold. The Study co-ordinator has written a note to file explaining this.
- Challenge:* At the VL site a protocol violation occurred on the 12th of December 2013 for PIN 464. An ineligible participant was recruited and enrolled. The participant participated in a focus group discussion conducted by RA04 and RA03. On the 13th of December 2013 upon updating the relevant data collection logs, the Study co-ordinator discovered that PIN 464 had been on product hold. The participant was recruited for CAP 106 on the 22nd of October 2013 on site and indicated to the RA that she is currently using product. The participant was not on the list of potential participants that the Study co-ordinator completed weekly in order to assist the CAP 008 administrators to identify participants for recruitment that meet the CAP 106 recruitment criteria as her visit to the clinic was not a scheduled CAP 008 visit. The RAs reported that in the FGD she also contributed to the discussion as if she was using the product.

Action: As corrective action, the study coordinator instructed the RAs that when contacting participants for future data collection events to first re-check their PINs with the study co-ordinator to ensure that the participant is not on product hold. Furthermore re-training was conducted with the CAP 008 administrators as well CAP 106 Research Assistants to remind them on the procedures to be followed for recruitment as per the SoP. A protocol violation report was filled and submitted to BREC on the 19th of December 2013.
- Challenge:* At the TK site it was discovered that 2 out of the 5 participants who participated in a FGD (CAPTK_2_FGD1) were in fact FP participants.

Action: The issue was escalated to the PI who advised the study co-ordinator to check if this incident was a protocol deviation. It was determined that this was not a protocol deviation. The PI has informed FHI and it was agreed that this data would be retained. The makeup of participants in the FGD will be considered during analysis.
- Challenge:* At the VL site, from the motivations guide some participants experienced difficulty in understanding two questions. The participants didn't understand the questions even when the moderator tried to explain them, the note taker had to assist in explaining these questions and participants still had problems understanding it.

Action: A Skype call was held with the FHI Site Co-ordinator and the RAs to discuss those two questions and how to better explain it to the participants.
- Challenge:* At the VL site, an issue was experienced with the first support FGD conducted. In summary, when the FGD began participants were trying to respond to some of the questions but as the FGD progressed they were becoming detached, to a point where only one or two participants were responding. At that point the moderator went on and would probe those who were not responding and they would say they are thinking the same thing that has been said by the participant who has responded.

Action: During a Skype meeting with the FHI Site Co-ordinator and the relevant RAs the issues encountered were discussed. It was agreed that this FGD would be treated as a pilot, not processed for data analysis and that the second support FGD be scheduled. The VL second support FGD went much better than the first so processing of that transcript was given the go ahead.

- Challenge:* Participants would often agree to take part in a FGD and then would not come to site at all or arrive much later than the scheduled time.

Action: The participants who did not arrive were contacted telephonically to check if they were still coming. In some cases IDIs were conducted with the participants that did arrive on time, if there were not adequate numbers for a FGD to be held. For future FGDs, pick up points were arranged and precise times to be picked up were communicated to participants, (given a small range of freedom). Further, efforts were made to ensure double the amount of participants were recruited for the FGD.
- Challenge:* At the VL site the RAs noted that staff members sometimes accidentally entered into the room where a data collection event was occurring without knocking.

Action: The RAs locked their room door and ensured a sign was placed on the outside of the door (do not disturb) when IDIs are being conducted. An email was sent by study coordinator to managers noting this problem and highlighting that confidential interviews are taking place in the CAP 106 office. They were requested to communicate this information to their teams. In addition this issue was highlighted at the Monday morning site staff meeting.
- Challenge:* At the TK site, during one of the IDI's the staff member noticed that the recorder was not switched on halfway through the IDI. As a result she restarted the IDI.

Action: It was stressed to the RAs that expanded notes should be collected for all IDI's in order to buffer for such cases. Therefore data will not be lost if the recorder malfunctions or is not switched on.
- Challenge:* Although participants did request to be interviewed at their home, the home environment was not always ideal. At the VL site, in the case of the one participant interviewed she had to care for 4 children and she had already spent a day at the 008 clinic that week asking her sister to look after the children.

Action: In order to cope with that situation the RA had to be innovative. When talking about sex, the children were present, they would use a different word for it for example 'biscuit'. The RA would also skip certain questions that were not appropriate to ask in front of the children and then go back to them later. For participants who have children who request to be interviewed at home, upon confirming the event they will be advised (if possible) to let a relative/friend look after the children for that time the interview is planned. Also given their home situation some participants would thus like to be interviewed on the same day as their 008 visit.

Data Processing, Storage and Transfer to FHI 360

Data processing

The F4 transcription program was used to transcribe IDIs/ FGDs. The transcription and translation occurred in a systematic process. Firstly the isiZulu interviews were transcribed verbatim from the audio recordings. After the isiZulu interviews were transcribed it went through a quality control check process of the original audio (QCA). After QCA, the transcripts were then translated from IsiZulu to English. Following translation, a further quality check (QCE) of the English translation of the transcript was conducted to ensure that the translation was within the context of what was discussed during the interview. Lastly, the transcript was sent to the study coordinator to conduct a final check, to verify correct formatting and send the transcript to FHI360.

Data Storage

All electronic files (e.g. transcripts) were password-protected and stored on password-protected computers at all times. Audio files were also stored on password-protected computers. All hard copies of data (e.g. informed consent forms, handwritten notes, transcripts) were stored in a locked filing cabinet in a double-locked facility. All precautions were taken to ensure that the folders/files were kept in good condition, e.g. that no water was spilt on them or the folders were damaged. Signed Informed Consent

Forms, Recruitment Forms and Master Study Log were kept separately in a locked filing cabinet, as they contained participant identifying information.

Transfer of Qualitative Data Files to FHI

All final data files, including final transcripts, expanded notes, field notes and abstracted data were transferred by the study co-ordinator/designee to Brian Perry, Data Manager, at FHI 360 via Leapfile. The date the final documents were sent to FHI 360 should be noted in the Data Collection Log.

Table 5: Data Processing

Data Processing Activity	# of transcripts transcribed	# of transcripts translated	# of transcripts transferred to FHI 360
CAP008 disclosed participants IDIs on adherence & continuation	39	39	39
CAP008 non-disclosed participants IDIs on adherence & continuation	24	24	24
Male partner IDIs on adherence & continuation	13	13	13
CAP008 participant IDIs on clinic experience	41	41	41
CAP008 provider/research staff IDIs on experience with HSS/QI and clinic service delivery	24	24	24
CAP008 participant non-discloser FGDs on acceptability & compliance	4	4	4
CAP008 participant discloser FGD on acceptability & compliance	5	5	5
Community men FGD on acceptability & compliance	4	4	4
Motivations FGDs	7	7	7
Support FGDs	2	2	2
Total # of transcripts	163	163	163

Challenges with data processing, storage and transfer and any action taken by the team to address those challenges

- Challenge:* One of the audio files on shared space (CAPVL_2_125) only played the first 2 minutes of the 1 hour file.
Action: Assistance was requested from the IT department who tried to run a few repair tests but no audio was picked up. The IT Department indicated that the audio recording was not salvageable.
- Challenge:* Transcription and more especially translation was challenging because some participants used colloquial language that RAs know but found difficult to explain better in English while making sure it remained within the context.
Action: The staff were encouraged to enquire the intended meaning and context from the RA that conducted an IDI/ FGD. All attempts were made to ensure that the RA that conducted the event conducted a quality check on the transcript.
- Challenge:* Miscomprehension of the context mostly by the students that were assisting in the weekends and the additional transcriber/translator staff who were employed later. Extensive review and quality control mostly obviated this but this was a tedious process.
Action: For future studies care should be taken to employ enough staff from the beginning to allow for them to get the same training to avoid unnecessary misunderstanding.

Study Close-out

The final monitoring and close out visit took place week of 12-16 May 2014. The last participant was recruited on the 6th of March 2014. Enrollment and data collection ended on the 16th of April 2014. Data processing and transfer to FHI was completed on 29th of April 2014.

Successful participant events were held at each site. A participant event was held at the VL site on the 22nd of May 2014. Of the 51 participants that confirmed their attendance, 40 arrived. The participant event was held at the TK site on the 30th of May 2014. Of the 28 participants that confirmed their attendance, 14 arrived. At these events participants were thanked for their participation and informed that once the results are finalised they would receive a handout at their next CAP 008 visit.

Other general challenges

- *Challenge:* The SSP and SOP's for this study did not include a version control log. The information is available if needed from different sources for example, ethics letter approval dates, in archival folders on document footers. However, there is no easy way to know which version document was approved for use in different periods. In some cases the same version number has different footer information.
Action: The SSP and SOP's for future qualitative studies should include a version control log.
- *Challenge:* The SSP and SOPs for this study as written had no central place that documents the reading and signing off of changes in protocol, SSP or guide versions. Signing off on documents was done in the training log but sometimes new documents were disseminated without an official training.
Action: The SSP and SOPs for future qualitative studies should include a central place that documents the reading and signing of such changes and newer versions.

Summary

This report sought to summarize important lessons learnt from this study for future qualitative study implementation. The key lessons for each sections are summarised below:

Sites

- Ensure the necessary infrastructure such as internet connectivity is in place early in the project implementation process.

Participant accrual/recruitment

- Certain target population categories were difficult to recruit such as partners and non-disclosed women. Following discussions with the CAP 008 and internal CAP 106 team measures were put in place to attempt to improve this.

Consenting and data collection

- Ensure the correct ICFs are used for the relevant participant type.
- It is important to have private and confidential spaces for events, as this affects the quality of the event and what information participants would feel free to share or not.
- Staff training and regular monitoring is important to ensure staff use the correct versions of documents.

Data processing, storage and transfer

- When dealing with audio recordings always check that the full recording has been downloaded on the computer prior to deleting it from the recorder.

- It is important to have the person that conducted the IDI/FGD, quality check the transcript to ensure the intended meaning and context of the event is not lost.

Other general challenges

- The SSP and SOPs for future studies should include a version control log and a central place that documents the reading and signing of document changes and newer versions.

All CAPRISA staff who worked on this project agreed that this was a good working and learning experience. The results from this important study will inform the design of a combined social-structural intervention to enhance acceptability, adherence, compliance, and continuation of TFV gel as an HIV prevention option for women.