VOICE	E-C S GROUP DISCUSSION GUIDE: Group 1	Date:	No. FGD_
Facilita	ntor Note taker: Venue:	_ Language: Zulu Sotho Gr	oup: Gel Tablet Participant #:
INSTRU	JCTIONS for the facilitator to understand – How to read this Foc	us Group Discussion Guide	
1.	There are 3 levels of questions:		
	 <u>Numerical research questions/topic areas highlighted in grey</u>: t be read aloud. 	he questions/areas that we as VOICE-C re	searchers want to get answers to. These don't need to
	• FGD questions: the questions that you as the facilitator will ask	respondents in order to get answers to the	e research questions.
	 <u>Probes:</u> they are indicated with a bullet, and will not be translat addressed/discussed during the FGD. So, depending on what 		
2.	Instructions/suggestions to facilitator are in italics.		
3.	The FGD guide is divided into three columns.		
	 The left-hand column contains the research questions, FGD q not required to read them verbatim, but they are written in local how the discussion develops. The facilitator will have to ensure 	language to ensure some consistency acro	oss FGD. You may adapt the question, depending on
	 The middle column is for questions for which there is likely to captures the group response to the research question. 	be consensus and a clear response from th	ne group. Please check the response options that best
	 The right-hand column is for summarising the themes. These responses of individual women in response to particular points sentences of bullet points. They do not need to be detailed, as the FGD by the note-taker, and then reviewed immediately and the reviewed imme	or questions. These summaries should be rewe have the details on the tape. Note: the	more than just yes/no, but not longer than a few
Before	starting the Focus Group Discussion, the facilitator explains to	the focus group:	
	We will begin the tape recorder now. [Facilitator: start the tape.]	recorder.]	
	 As you know from your informed consent, this FGD will be tape session and that it is okay with you. [Facilitator: be sure to get a 		

VOICE-C	Date: U/U		No. FGD_LLL	
FOCUS GROUP DISCUSSION GUIDE: Group 1 COMMUNITY FACTORS				
1. Identify rumours and stories about VOICE and the effect on				
trial participants ENGLISH:				
What have you heard people say about the VOICE study in your	Did rumours/ stories			
community and what has been the effect on VOICE participants?	influence			
05007110.	participants'			
SESOTHO: Ke eng tse o di utlwileng batho ba bua ka tsona ka ha dipatlisiso tsa	adherence to product and clinical			
VOICE mo motseng wa heno? Le hona se se amile jwang	procedures?			
bankakarolo dipatlisisong tsa VOICE?				
1017111.11.	□Yes			
ISIZULU: Uzwe abantu bethini ngocwaningo lwe VOICE kumphakathi wakho?	□No	-		
Futhi lokho kube nomphumela onjani kubantu ababambe ighaza				
kucwaningo lweVOICE?				
Is there:				
 widespread knowledge/awareness of the VOICE study or 				
other medical research in the community?		-		
 Describe the rumours or stories about VOICE: specify who, 				
what, when, where, why?				
Are these always negative rumours or are some positive?How widespread are these rumours?				
 Do you believe these rumours/stories? 				
 How did women in the VOICE study react to these rumours / 				
stories? (e.g.: talked to others about them, changed trial				
 attendance, changed gel/tablets use) Were rumours started by anything specific? E.g.: media 				
 Do you think that the rumours about VOICE had any impact 				
on your ability to use gel/tablets as directed by the VOICE				
staff?				
Additional probes:				
 How did you find out about the VOICE results? What did you hear other people in your community saying about the VOICE 				
results? How did you feel about what they were saying?				

No. FGD_LLL **VOICE-C FOCUS GROUP DISCUSSION GUIDE: Group 1** 2. How did the local environment influence gel/tablets adherence? Influence of the environment on **ENGLISH:** product use? What sorts of things about the area you live in helped or hindered women's daily use of gel/tablets in the VOICE study? □Positive influence □Negative influence SESOTHO: □No influence Ke dintho tsa mofuta mang mo tulong eo o dulang ho yona tse thusitseng kapa tse sitetseng basadi ho sebedisa jele/dipilisi letsatsi le letstatsi mo dipatlisisong tsa VOICE? ISIZULU: Ingabe yiziphi izinto kwindawo ohlala kuyona ezithe zasiza noma zaphazamisa abesifazane ukuthi basebenzise nsuku zonke ijel/amaphilisi ocwaningo lweVOICE,? • Logistical issues (i.e. job flexibility, public transportation, having transport money in advance?) Privacy and discreetness (i.e.: carrying products, attending

the clinic which is associated with HIV)

The scheduling of clinic visits (time of day, day of the week)
 Dangerous places – is the route to the clinic dangerous?

VOICE-C FOCUS GROUP DISCUSSION GUIDE: Group 1	Date:		No. FGD_
ORGANIZATIONAL FACTORS			
3. What motivated participants to join the VOICE study			
<u>ENGLISH:</u>			
What were your main reasons for joining the VOICE study? And did your motivation change over the course of the VOICE study?			
SESOTHO:			
Ke mabaka afe a bohlokwa a entseng hore o kenele dipatlisiso tsa			
VOICE? Le hona e kaba morero wa hao o ile wa fetoha ha dipatlisiso di tswela pele?			
ISIZULU:			
Ingabe kwakuyiziphi izizathu zakho ezisemqoka ezenze ukuthi			
ubambe iqhaza kucwaningo lweVOICE?. Ingabe ukukhuthazeka kwakho kuye kwashintsha ngokuhamba kwesikhathi socwaningo			
lweVOICE?:			
 Feeling at risk of acquiring HIV 			
 HIV VCT services 			
 Receiving free medical care, treatment, contraception (note: need to explain the difference between 'care' and 'treatment'. 			
 Learning safer sex practices 			
 Getting protected from HIV, STIs, pregnancy 			
Cash for transportAccess to the study product			
 To help to fight HIV and for the common good 			
4. What were women told at the study clinic and what did they say to staff about their gel/tablets use?	Accurate understanding of		
say to stail about their gentablets use:	product use?		
<u>ENGLISH:</u>	□ Maath.	-	
What information or messages did you receive from the clinic staff	☐ Mostly☐ Some		
on how to use gel/tablets?	☐ Little/none		

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Staff Initials & Date_____

VOICE-C	Date: U/ U	No. FGD_LLL
FOCUS GROUP DISCUSSION GUIDE: Group 1		
SESOTHO:	□ No consensus	
Ke lesedi lefe kapa melaetsa efe eo basebeletsi ba kliniking ba o		
fileng, ya hore o sebedise jwang jele/dipilisi?	Comfortable	
	reporting accurate	
<u>ISIZULU:</u>	product use?	
Ingabe yiluphi ulwazi noma imilayezo oyitholile kubasebenzi		
basemtholampilo mayela nokuthi isetyenziswa kanjani	□ Very	
<u>ijel/amaphilisi?</u>	□ Not very	
	□ Not at all	
 Clinic staff doesn't know if study product is effective or not 		
(study product is investigational)		
Insertion of gel (timing, dosage/amount incorrect insertion)		
 Taking tablets (timing, alteration of tablets, under/ over- 		-
dosage, vaginal insertion)		
 Did you understand the instructions? 		
 What happened if women didn't comply? What did the nurse/ 		
clinic staff say or do?		
How truthful were women about adherence behaviours?		
Were there consequences if women said they forgot or didn't		
take/use product? e.g. did staff reprimand women?		
What type of information/ counselling was helpful?		
 Is there anything you think study staff should tell others that 		
they didn't tell you?		
Additional probes		
What did the staff at the VOICE clinic tell you about the		
VOICE (DSMB) results? What did you understand by what		
they told you? How satisfied are you with this information?		
For those continuing in the trial (Oral Truvada group/Vaginal		
group):		
How do you feel about the light blue tablets being		
discontinued?		
 How does this change your use of your [other] study 		
products?		
For those in the oral TDF group:		
 What is your experience of being discontinued from VOICE? 		

VOICE-C	Date:	No. FGD_LLL
FOCUS GROUP DISCUSSION GUIDE: Group 1		
5. How did peers (at the clinic and outside) influence product use?		
ENGLISH: What kinds of things about the study and the gel/tablets did women discuss with each other, and did this influence their product use?		
SESOTHO: Ke dintho tsa mofuta ofe ka dipatlisiso le tshebediso ya jele/dipilisi tseo basadi ba ne ba buisana ka tsona, mme sena se bile le susumetso efeng tshebedisong ya dihlahiswa tsena?		
ISIZULU: Ingabe yiziphi izinto ezimayelana nocwaningo kanye nejel/amaphilisi abantu besifazane abaxoxisana ngazo nabanye, Futhi ingabe lokho kube nomthelela ekusetshenzisweni kwemikhiqizo?		
 At the study clinic (for example, in the waiting area) At other women's gathering (i.e. churches, women's groups, friends' homes etc.) What was said? By whom? When and where? Did this in any way influence adherence to product or to clinical procedures? 		

VOICE-C	Date:	No. FGD_
FOCUS GROUP DISCUSSION GUIDE: Group 1 HOUSEHOLD FACTORS		
6. Did the home environment influence adherence to study product?		
ENGLISH: What aspects of your home, made it easy or difficult to insert the gel daily/ take the tablet daily?		
SESOTHO: Ke dintho tsa mofuta mang ka lapeng tseo di thusitsego kapa di sitetseng basadi ho kenya jele letsatsi le letsatsi/ nka dipilisi letsatsi le letsatsi?		
ISIZULU: Ingabe yiziphi izinto zasekhaya ezenze kwabe lula noma zenza kwabe nzima ukufaka ijel nsuku zonke / ukuthatha amaphilisi nsuku zonke?		
 Where did you store the gel/tablets? Did this pose any problems? Where did you dispose of used applicators/ empty bottles? Did this pose any problems? Competing household obligations (daily duties/ chores/caregiving to sick family members) Crowding Access to water 		

Family income/ financial resources

VOICE C	Date:	No. FGD
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FOCUS GROUP DISCUSSION GUIDE: Group 1		
7. Influence of other household members on adherence.		
ENGLISH: How did the people who you live with (aside from your husband/main partner) influence adherence to the gel/tablets? SESOTHO: Ke susumetso e feng eo batho ba o phelang le bona (o sa akaretse monna/molekani e moholo wa hao) ba nang le yona hore o sebedisa jele/dipilisi hantle?	Household members generally supportive? Yes □ No □	
ISIZULU: Ingabe abantu ohlala nabo (ngaphandle komyeni /uphathini wakho) babe namuphi umthelela ngokusetshenziswa kahle kwejel/amaphilisi?		
 Disclosure about study and products: to whom and how – eg. 'voluntary' disclosure or accidental disclosure. What did they disclose (exactly)? What was the motivation to disclose? Role of other household members in sexual decision making, use of product and condoms How did they show their support or lack of support? Did anyone in the household use your gel/tablets? (Explain) Did anyone in the household help remind you to use your study products? (Explain) Additional probe: Did you tell anyone (partner, friend, household members, colleagues, etc) about the VOICE (DSMB) results? For TDF arm only: That you are off the study product? What did you say? How did they react? What did they say? 		
What concerns did they raise?		

VOICE-C FOCUS GROUP DISCUSSION GUIDE: Group 1 MALE PARTNERS	Date:	No. FGD_
8. How does decision-making impact on sex, condom and product use?		
ENGLISH: Who made decisions about having sex, condom use, about gel/tablets use?		
SESOTHO: Ke mang a neng a nka diqeto hore o etswe tsa thobalano, ho sebedisa dikondomo, le ho sebedisa jele/dipilisi?		
ISIZULU: Ubani kade enza izinqumo malunga nokuya ocansini, ukusebenzisa ikhondomu, noma ukusetshenziswa kwejel/amaphilisi?		
 What things are decided jointly? How is decision-making different for different issues? How are decisions made and who has the final say? How did male partners influence condom use and gel/tablets use? 		

VOICE-C	Date:	No. FGD	
FOCUS GROUP DISCUSSION GUIDE: Group 1		_	
9. Did male partners influence product adherence?	Partners generally		
ENGLISH: How did male partners influence the way women used the gel/tablets?	supportive of product use?		
SESOTHO: Balekane ba ba batona ba ne ba susumeditsa jwang ka tsela eo basadi ba neng ba sebedisa jele/dipilisi?	□ No □ No consensus		
ISIZULU: Ingabe abangane besilisa babe nomthelela onjani kwindlela abesifazane abasebenzise ngayo ijel/amaphilisi?			
What kind of things did women disclose to partners about study product use?			
 What were the consequences of disclosure or of non-disclosure? Was the disclosure accidental or intended, and when (at what stage of participation in the trial) did this take place? How did male partners show support or lack of support? Did male partners ever take away women's study products? For what reason (To use them? To throw them away?) Did product use generate or intensify conflicts between partners? (What type of conflicts? Explain when and how) 			

VOICE-C	Date:	No. FGD
FOCUS GROUP DISCUSSION GUIDE: Group 1		_
10. Were male partners generally supportive of study participation?	Partners generally supportive of study	
p.m.e	participation?	
ENGLISH:		
How did male partners influence whether women joined the VOICE	- W	
study?	☐ Yes	
SESOTHO:	☐ No☐ No consensus	
Balekane ba batona ba bile le susumetso jwang hore basadi ba kene	INO CONSCIISUS	
kapa ba se kene dipatlisisong tsa VOICE?		
ISIZULU:		
Abangane besilisa babe nomthelela onjani ekutheni abesifazane bangene noma bangangeni kucwaningo lweVOICE?		
bangene noma bangangen kacwaningo we voice:		
 Male partner(s) role on women's ability to join the 		
study/attend visits		
 What kinds of things did women disclose to male partners 		
about study activities?What were the reactions and consequences of disclosure or		
of non-disclosure?		
 Was the disclosure accidental or intended, and when (at what 		
stage of participation in the study) did this take place?		
 What were men's reasons for supporting or not supporting 		
their female partners' participation in the study?		
 Did joining the VOICE Study generate or intensify conflict between partners? (What type of conflicts? Explain when and 		
how)		
,		

VOICE-C	Date: Date: No. FGD_D
FOCUS GROUP DISCUSSION GUIDE: Group 1	
11. What were male partners' concerns re: the gel/tablets? ENGLISH: What concerns did male partners have regarding women using the gel/tablets? SESOTHO: Ke dingongoreho dife tseo balekane ba senna ba bileng le tsona ha ne basadi ba bona ba sebedisa jele/dipilisi? ISIZULU:	Male partners' main concern: Themselves Female partner No consensus
 Yini beyikhathaza abalingani besilisa mayelana nokuthi abalingane babo besifazane basebenzisa ijel/amaphilisi? Concerns about their female partners (her fidelity, side effects/her being sick, her sexual enjoyment, fertility) Concerns that product is female-initiated. Concerns about themselves? Safety concerns such as short term effects (e.g., rash, itching) or long term effects on pregnancy and the health of a future baby, fertility, effects on penis, effects on sperm? Concerns about taking antiretroviral treatment as a preventative measure. 	

VOICE-C	Date:		No. FGD_
FOCUS GROUP DISCUSSION GUIDE: Group 1			_
ACCEPTABILITY			
12. Were the gel/tablets generally acceptable to participants?	Acceptable?	-	
ENGLISH: What did women in the VOICE Study like and dislike about the gel/tablets?	☐ Yes☐ No☐ No consensus		
<u>SESOTHO:</u> Ke eng seo basadi dipatlisisong tsa VOICE ba neng o se rata kapa o sa se rate ka jele/dipilisi?			
ISIZULU: Yikuphi abesifazane abakucwaningo lweVOICE abakuthandile kanye nabangakuthandile malunga nejel/amaphilisi?			
 Negative / undesirable effects (vaginal, bodily) Positive / desirable effects (taste, smell, size, lubrication) Emotional changes Physical changes Convenience of use Use of gel/tablets for other purposes (e.g.: gel as skin cream) 			
 Additional probes: (For TDF arm only) What did you think about the tablets while you were using them? For Truvada arm only: How have your feelings changed now that you have heard that the light blue tablets will be discontinued? 			

VOICE-C	Date:		No. FGD_	
FOCUS GROUP DISCUSSION GUIDE: Group 1 GEL ADHERENCE				
13. Were the gel/tablets generally consistently used?		-		
ENGLISH: Were women in the VOICE study usually able to use their gel/tablets every day or not? SESOTHO: Ekaba basadi mo dipatlisisong tsa VOICE ba ne ba sebedisa iele/dipitlisi letsatsi le letsatsi kapa tihe? ISIZULU: Ingabe abesifazane abakucwaningo lwe VOICE babenakho njalo nje ukusebenzisa ijel yabo/amaphilisi wabo nsuku zonke noma cha? Differences at the start, middle, end of the study? If change over time, then why? Who were more / less adherent and for what reasons? When partner away/ woman away When not having sex When feeling sick When using other medications During menstruation When products ran out Other Reasons (Forgot, Didn't feel like it) Life event: e.g. death in the family, move, new job etc Ever use another product in place of the study gel/tablets like another product from the store or a friend's gel/tablets? Why? Additional probe: What do you think brought about the VOICE (DSMB) results? Do you think the outcome is because of the tablet not being effective or the ways in which participants used the tablet or	Consistently used? Yes No No consensus			
something else?				

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VOICE-C	Date: U/U	No. FGD_LLL	
FOCUS GROUP DISCUSSION GUIDE: Group 1			
14. What adherence levels would be acceptable in "real life" for the study products?			
ENGLISH: What level of product adherence can be expected in "real life" if women were to use gel/tablets for HIV prevention outside of a trial?			
<u>SESOTHO:</u> <u>Ke maemo afe a ho sebedisa setsweletswa hantle a ka lebellwang bophelong ba nnete ha eba basadi ba ne ba sebedisa jele/dipilisi ho thibela twatsi ya AIDS ba se mo dipatlisong?</u>			
 Ingabe yiliphi izinga lokusetshenziswa kahle (nsuku zonke) komkhiqizo elingalindelwa kwimpilo yenjwayelo, uma abesimame bebengasebenzisa ijel/amaphilisi wocwaningo ukuvimba isandulela ngculazi, ngaphandle kokubamba iqhaza kucwaningo? Could women use the product daily over several months? When would it be impossible to use the products? When would it be okay to not use the product? (specific circumstances: when travelling, when partner away, specific types of relationships-new, established partners) 			

VOICE-C	Date:		No. FGD_		
FOCUS GROUP DISCUSSION GUIDE: Group 1			_		
STUDY PRODUCTS AND RISK TAKING BEHAVIOUR					
15. Did gel/tablets use influence sexual behaviours, relationships and contraception?	Products changed sexual behaviours?				
ENGLISH:	benaviours:				
How did gel/tablets use change women's sexual behaviours, relationships, and use of contraceptives during the VOICE study?	☐Yes ☐Somewhat				
SESOTHO:	□No				
Na tshebediso ya jele/dipilisi e fetotse maitshwaro o tsa thobalano ya basadi, dikamano, le tshebediso ya dithibelapelehi ka nako ya mo					
dipatlisiso tsa VOICE?					
<u>ISIZULU:</u>					
Ukusebenzisa ijel/amaphilisi kukushinshe njani ukuziphatha					
kwabesifazane mayela nezocansi, ubungane, ukusebenzisa uhlelo lomndeni ngesikhathi bekucwaningo lweVOICE?					
 Anal or oral sex Condom use (during the trial, after PUEV) Contraception Type or number of sexual partners How often you have sex Reasons for having sex (transactional sex, for pleasure, for procreation) Additional probes: (for TDF arm only): How does stopping to use the tablet change your sexual behaviour condom use relationships use of contraception? What are you going to do about this? 					

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Staff Initials & Date_____

VOICE-C FOCUS GROUP DISCUSSION GUIDE: Group 1 VAGINAL PRACTICES & PRODUCT PREFERENCE

16. Did gel/tablets use influence hygiene or vaginal cleansing practices?	Products changed vaginal practices?	
ENGLISH: While you were using the gel/tablets did you change your hygiene and vaginal cleansing practices?	☐ Yes ☐ No ☐ No consensus	
<u>SESOTHO:</u> Ha ne o sebedisa jele/dipilisi o ile wa fetola ditlwaelo tsa bohlweki le ditlwaelo tsa o hlwekisa setho sa sesadi?		
<u>ISIZULU:</u> Ngesikhathi usebenzisa ijel/amaphilisi,uye washinsha indlela yokuzicoca neyokuhlanza isitho sakho sangasese?		
 Did women find that they needed to wash or clean their vagina more or less while on product? Why? Were women able to add gel/tablets use into their daily routine of hygiene and vaginal cleaning? If yes, how did they manage? Did counselling from the study influence these practices? After joining the VOICE study, what happened to vaginal cleansing practices before or after sex? Did anything change? 		

VOICE-C	Date:		No. FGD_	
FOCUS GROUP DISCUSSION GUIDE: Group 1				
17. Did preferences develop among the women over gel vs. tablets?	Product preference?			
ENGLISH: Was either the tablets or the gel perceived to be more preferable among the women in the VOICE study?	☐ Gel preferred ☐ Tablets preferred ☐ No clear ☐ preference			
SESOTHO:				
Ekaba mahareng ha jele le dipilisi ho na le eo e neng e bonahala e thabelwa haholo hara basadi mo dipatlisisong tsa VOICE?				
triaboliva harroto hara babaar mo dipatiloloonig tod voloc.				
<u>ISIZULU:</u>				
Ingabe bekuyijel noma amaphilisi ababonakele bekukhetha kakhulu				
abantu besifazane abakucwaningo lweVOICE?		-		
Did you like or dislike the group you were randomized to?				
 Were there attempts among the women to try the other product and exchange tablets for gel? 				
 Did the gel do things to the body that the tablets didn't (or vice versa)? 				
 Were there common side effects among women and did these differ among gel and tablet? 				
 Discuss issues surrounding discreteness and female-initiation for gel versus tablets. 				
What is viewed as preferable in this community: an HIV prevention product inserted in the vagina (gel) or taken orally (tablets)?				

	/	
VOICE-C	Date: LLL	No. FGD_LLL
FOCUS GROUP DISCUSSION GUIDE: Group 1		
18. Any other questions?		
ENGLISH: Is there anything else you would like to tell me about the study products or your experience using the gel/tablets?		
<u>SESOTHO:</u> Ekaba ho na le se seng hape se le ratang ho bua le nna sona ka ha dihlahiswa tsa dipatlisiso kapa maiphihlelo a lena ka tshebediso ya jele/dipilisi?		
 ISIZULU: Ingabe ikhona enye into ongathanda ukungitshela yona ngemikhiqizo yocwaningo, noma izipiliyoni zakho zokusebenzisa ijel/amaphilisi? Ask if they have any questions for you 		
TO BE COMPLETED BY NOTE TAKER/FACILITATOR AFTER FGD COMPLETED: Please write general comments about mood, how the discussion went, participants' level of comfort/openness etc	General flow of this FGD: □ Easy □ Difficult Participants were comfortable and	
	talked easily? □ All □ Some □ None	