

IN-DEPTH INTERVIEW GUIDE: Group 1

Facilitator Note taker: Venue: _____ Language: Zulu Sotho English Group: Gel Tablet PTID: **INSTRUCTIONS For the interviewer to understand – How to read this IDI Guide**

1. There are 3 levels of questions:
 - Numerical research questions/topic areas highlighted in grey: the questions/areas that we as VOICE-C researchers want to get answers to. These **don't** need to be read aloud.
 - IDI questions: the questions that you as the interviewer will ask respondents in order to get answers to the research questions. These questions will be underlined.
 - Probes: they are indicated with a bullet, and will not be translated. The interviewer should ensure that key topics listed in the probes have been addressed/discussed during the interview. So, depending on what has already been discussed, and the IDI context, you may ask these probes or not
2. *Instructions/suggestions to interviewer are in italics.*
3. The IDI guide is divided into three columns.
 - **The left-hand column** contains the research questions, IDI questions and probes. The IDI questions are suggestions for getting the discussion going. It is not required to read them verbatim, but they are written in local language to ensure some consistency across IDIs. You may adapt the question, depending on how the interview develops, and the interviewer will have to ensure that at the end the research questions have been answered.
 - **The middle column** is for the interviewer to complete after the IDI, and to capture (where appropriate) the key answer (yes/no) addressing the research question.
 - **The right-hand column** is for summarising the themes brought up by the woman in the IDI. These should be summaries of the general issues raised in connection with the research question. These summaries should be more than just yes/no, but not longer than a few sentences or bullet points. They do not need to be detailed, as we have the details on the tape. **Note: the summaries and yes/no answers should be filled by the IDI interviewer immediately after the IDI.**

Before starting the IDI, the Interviewer explains to the respondent (please state verbatim):

- We will begin the tape recorder now. [*Interviewer: start the tape recorder.*]
- As you know from your informed consent, this IDI will be tape recorded today. Please verbally indicate that you are aware that we are tape recording this session and that it is okay with you. [*Interviewer: be sure to get a verbal okay from the respondent.*]

COMMUNITY FACTORS**1. Identify rumours and stories about VOICE, and effect on participant**ENGLISH:

What have you heard people say about the VOICE study in your community, and how does this affect you?

SESOTHO:

E kaba o utlilwe batho ba bua eng ka dipatlisiso tsa VOICE mo motseng wa heno le hona seo se o tshwara jwang?

ISIZULU:

Yini oke wayizwa abantu beyisho ngocwaningo lwe-VOICE kumphakathi wakho? Lokho kukuthinta kanjani?

- 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?
- How widespread are these rumours?
- Do you believe these rumours/stories?
- Are these always negative rumours or are some positive?
- How have you reacted to these rumours/stories? (e.g.: talked to others about them, changes in trial attendance, and changes in gel / tablet use)
- Were rumours/stories started by anything specific? E.g.: media
- Do you think that the rumours/stories about VOICE have any impact on your ability to take gel/tablets as directed by the VOICE staff?
- How do you feel about the CAPRISA 004 results?

Did rumours/ stories influence participants' adherence to product and clinical procedures?

- Yes
 No

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<p>2. How does the local environment influence gel/tablets adherence?</p> <p><u>ENGLISH:</u> What sorts of things about the area you live in help or hinder your daily use of gel/tablets in the VOICE study?</p> <p><u>SESOTHO:</u> Ke dintho tsa mefuta mang tulong eo o dulang ho yona di o thusang kapa di o sitisang ho sebedisa jele/dipilisi letsatsi le letsatsi mo dipatlisisong tsa VOICE?</p> <p><u>ISIZULU:</u> Yiziphi izinto endaweni ohlala kuyo ezisiza noma eziphazamisana nokuthi usebenzise nsuku zonke ijel/amaphilisi ocwaningo lwe-VOICE?</p> <ul style="list-style-type: none"> ▪ 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 – e.g.: is the route to the clinic dangerous? 	<p>Influence of the environment on product use?</p> <p><input type="checkbox"/> Positive influence</p> <p><input type="checkbox"/> Negative influence</p> <p><input type="checkbox"/> No influence</p>	
<p>3. Is there any product sharing, taken, stolen or sold?</p> <p><u>ENGLISH:</u> Has there been any instances in which your study products have been taken without your permission, shared or given to other people who wanted them?</p> <p><u>SESOTHO:</u> E kaba ho ile wa etsahala hore jele/dipilisi tsa hao di ile tsa sebediswa kapa tsa arolelwa batho ba bang ntle ha tumello ya hao?</p>	<p>Product shared/taken/sold</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>	

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<p><u>ISIZULU:</u> <u>Ingabe kuke kwabakhona yini izigameko lapho imikhiqizo yakho yocwaningo ike yathathwa ngaphandle kwemvume yakho, yabelwa noma yanikwa abanye abantu abayidingayo?</u></p> <ul style="list-style-type: none"> ▪ Have you been in a situation where you shared or gave products to other people? Who, when and how did this happen? ▪ Have you been in a situation where people have taken or stolen the products from you? Do you know for what reasons? 		
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ORGANIZATIONAL FACTORS

<p>4. What motivated the participant to join the VOICE study?</p> <p><u>ENGLISH:</u> <u>What were your main reasons for joining the VOICE study?</u></p> <p><u>SESOTHO:</u> <u>Ke mabaka afe a bohlokwa a entseng hore o kenele dipatlisiso tsa VOICE?</u></p> <p><u>ISIZULU:</u> <u>Kwakuyiziphi izizathu zakho ezisemqoka zokuthi uzibandakanye nocwaningo lwe-VOICE?</u></p> <ul style="list-style-type: none"> ▪ Because you felt that you were 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 transport 		
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VOICE-C

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No. IDI_

<ul style="list-style-type: none">▪ Access to the study product▪ To help to fight HIV and for the common good		
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<p>5. How acceptable are the VOICE study procedures and how this influenced study visits?</p> <p><u>ENGLISH:</u> <u>What do you like and what do you dislike about participating in VOICE?</u></p> <p><u>SESOTHO:</u> <u>Ke eng se o se rateng le se o sa se rateng ka ho nka karolo dipatlisisong tsa VOICE?</u></p> <p><u>ISIZULU:</u> <u>Yikuphi okuthandayo kanye nongakuthandi ngokuzimbandakanya kwakho kucwaningo lwe-VOICE?</u></p> <ul style="list-style-type: none"> ▪ <u>Adherence counselling session (what helps or doesn't help, initially at enrolment and later during each FU)</u> ▪ Clinic staff ▪ The clinic environment ▪ The waiting times ▪ The physical procedures ▪ The other participants ▪ How did study procedures influence your decisions about coming back for your visits? ▪ Concerns regarding using the product containing ARV (side-effects) 	<p>VOICE study procedures acceptable?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>6. Do participant experiences at the study clinic influence product adherence behaviours?</p> <p><u>ENGLISH:</u> <u>Would you say that your experiences with the staff and of the study procedures in general help or hinder your ability to use the gel/tablets?</u></p>	<p>Study clinic helps adherence?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

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<p><u>SESOTHO:</u> <u>A o kare boiphihlelo ba hao le basebeletsi ba dipatlisiso le ditsamaiso tsa dipatlisiso ka kakaretso di o thusitse kapa di o sitetse ho khona ha hao ho sebedisa jele/dipilisi?</u></p> <p><u>ISIZULU:</u> <u>Ungasho yini ukuthi izipiliyoni zakho nabasebenzi kanye nendlela yenqubo yocwaningo kuyasiza noma kuvimba ukuthi ukwazi ukusebenzisa ijel/amaphilisi?</u></p> <ul style="list-style-type: none"> ▪ What did the clinic staff say or do that most encouraged/discouraged you to take daily the gel/tablets? ▪ Quality of services ▪ Relationships with other participants/waiting room discussion ▪ Access to the clinic ▪ Understanding of clinical study procedures ▪ Messages received regarding protection from study products 	<input type="checkbox"/> No influence	
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HOUSEHOLD FACTORS

<p>7. Did the home environment influence adherence to study product</p> <p><u>ENGLISH:</u> What aspects of your home, make it easy or difficult to insert the gel daily / take the tablet daily?</p> <p><u>SESOTHO:</u> Ke dintho tsa mofuta mang ka lapeng tseo di thusang kapa di sitelang hore o kenye jele letsatsi le letsatsi / nke dipilisi letsatsi le letsatsi?</p> <p><u>ISIZULU:</u> Yiziphi izingxenye zekhaya lakho ezenza kube lula noma kube nzima ukufaka ijel nsuku zonke / ukuthatha amaphilisi nsuku zonke?</p> <ul style="list-style-type: none"> • 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 		
<p>8. Does mobility have an effect on adherence to study product or clinical procedures?</p> <p><u>ENGLISH:</u> Do changes in the place where you sleep and live influence your</p>	<p>Mobility impacts product adherence and clinic</p>	

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<p><u>using the gel/ taking tablets and attending the clinic?</u></p> <p><u>SESOTHO:</u> E kaba ho fetoha fetoha ha thulo eo o robalang le ho dula ho yona ho na le tshusumetso ho <u>sebediseng jele/ enkeng dipilisi</u> le ho tla kliniking?</p> <p><u>ISIZULU:</u> Ingabe ukushintsha kwendawo olala kuyona nalapho uhlala khona kunomthelela <u>ekusebenziseni kwakho ijel/ ukuthatha amaphilisi</u>, nokuya emtholampilo?</p> <ul style="list-style-type: none"> • Do you always sleep in the same place • Do you often move your home • Do you visit friends or relatives for long periods of time • Does changing your residence influence your adherence to <u>gel/tablets</u> or study procedures? 	<p>attendance?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> NA</p>	
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<p>9. Influence of other household members on adherence</p> <p><u>ENGLISH:</u> How do the people who live with you (aside from your husband/main partner) influence your adherence to the gel/tablets?</p> <p><u>SESOTHO:</u> Ke tshusumetso e feng eo batho batho ba o phelang le bona (o sa akaretse monna/molekani e moholo wa hao) ba nang le yona hore o sebedisa jel/dipilisi hantle?</p> <p><u>ISIZULU:</u> Ingabe abantu abahlala nawe (ngaphandle komnyeni wakho noma isoka lakho eliqondile) banomthelela onjani ekusebenziseni kwakho ngendlela ijel/amaphilisi?</p> <ul style="list-style-type: none"> • 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? • Who are they (relationship to you)? • Role of other household members in sexual- decision making, use of product and condoms • How do 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 take your study products? (Explain) 	<p>Household members generally supportive?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
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MALE PARTNERS

<p>10. How does decision-making impact on sex, condom and product use?</p> <p><u>ENGLISH:</u> Who makes decisions about having sex, condom use, about</p>		
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<p><u>gel/tablets use?</u></p> <p><u>SESOTHO:</u> Ke mang a neng a nka digeto hore o etswe tsa thobalano, ho sebedisa kondomo, le ho sebedisa <u>jele/dipilisi?</u></p> <p><u>ISIZULU:</u> Ubani owenza izinqumo ngokuya ocansini, ukusetshenziswa kwekhondomu, ukusetshenziswa <u>kwejel/amaphilisi?</u></p> <ul style="list-style-type: none"> • Current partner details and type of relationship; changes in relationships (e.g. new primary partner) • What things are decided jointly? • How is decision-making different for different issues? • How are decisions made and who has the final say? • How does male partners influence condom use and <u>gel/tablets use?</u> • Differences in terms of types of partnership (casual, one night stand, long term, paying client) 		
<p>11. Does her primary partner have an influence on adherence and study participation?</p> <p><u>ENGLISH:</u> <u>How does your primary partner influence your joining the VOICE study and using study products?</u></p> <p><u>SESOTHO:</u> <u>Molekane wa hao wa sebele o na le tshusumetso jwang tabeng ya hore o kene hoba ba se kene dipatlisong tsa VOICE le ho sebedisa sehlahiswa sa dipatlisiso?</u></p> <p><u>ISIZULU:</u> <u>Ingabe umuntu othandana naye unomthelela onjani ekuzimbandakanyeni kwakho nocwangingo lweVOICE kanye</u></p>	<p>Primary Partner generally supportive?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>	

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<p><u>nokusebenzisa imikhiqizo yocwaningo?</u></p> <ul style="list-style-type: none"> • Partner's role in encouraging/ discouraging enrolment in study/ attend visits • Disclosure or non-disclosure to partner regarding participation on the trial and the consequences of this? • Was disclosure accidental or purposeful (intended) • Disclosure to partner regarding product use and the consequences of this? • Did your male partner ever take away your study products? For what reason (to use them? To throw them away?...) • Partner conflicts in general • Did joining the VOICE study or using products generated or intensified conflicts between you and you partner? (What type of conflicts? Explain when and how) • How does partner show support or lack of support (e.g. reminding you to take product, request to share product) 		
<p>12. What are male partners' concerns re: the gel/tablets?</p> <p><u>ENGLISH:</u> <u>What concerns does your primary partner have regarding you using the gel/tablets?</u></p> <p><u>SESOTHO:</u> <u>Ke dingongoreho dife tseo molekane wa hao wa sebele a nang le tsona ha o sebedisa jele/dipilisi?</u></p> <p><u>ISIZULU:</u> <u>Ingabe yiziphi izinto ezingaphathi kahle umuntu othandana naye mayelana nokuthi usebenzisa ijel/amaphilisi?</u></p> <ul style="list-style-type: none"> • Concerns about you: fidelity, side effects/ being sick, her sexual enjoyment) 		

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- Concerns that product is female-initiated
- Concerns about himself?
- 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 prevention?

PRODUCT ACCEPTABILITY

13. How acceptable are the gel/tablets to participants?ENGLISH:

What do you like and dislike about using the gel/tablets?

SESOTHO:

Ke eng se o se ratang kapa o sa se rateng ka tshebediso ya **jele/dipilisi**?

ISIZULU:

Yini oyithandayo kanye nongayithandi ngokusebenzisa **ijel/amaphilisi**?

- Negative / undesirable side effects (vaginal, bodily)
- Positive / desirable effects (taste, smell, size, lubrication)
- Emotional changes
- Physical changes
- Convenience of use
- Use of gel/tablet for other purposes (e.g.: gel as skin cream)
- What do you think the is preferable for HIV prevention: the gel or the tablets?

Acceptable?

- Yes
 No

14. Main reason for using gel/tabletsENGLISH:

What are your main reasons for using the gel/tablets?

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SESOTHO:

Ke mabaka afe a bohlokwa a entsang hore o sebedise **jel/dipilisi**?

ISIZULU:

Yiziphi izizathu zakho ezisemqoka zokusebenzisa **ijel/ amaphilisi**?

- Perceived efficacy or lack of efficacy of products?
- Beliefs of protection against HIV?
- Fear of being shouted at by nurse
- Believes that gel/tablets do something else to me
- Makes her feel good/bad

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PRODUCT ADHERENCE

15. Does she use the gel/tablets consistently?

ENGLISH:

Are you usually able to take your gel/tablets every day or not?

SESOTHO:

E kaba o atisa ho sebedisa jele/dipilisi letsatsi le letsatsi kapa na ha o jwalo?

ISIZULU:

Ingabe uyakwazi njalo nje ukuthatha ijel/amaphilisi akho nsuku-zonke noma cha?

- Do you always, sometimes, hardly ever, never take the tablet / gel everyday?
- When do you usually take the tablet / insert the gel, and why?
- How do you remind yourself?
- Why do you sometimes not use the gel / take your tablets?
 - Relationship problems (with your main partners, with family members, with other household members)
 - When not staying at home
 - When partner away
 - When not having sex
 - When feeling sick
 - When using other medications
 - During menstruation
 - When products ran out
 - Forgetting
 - Did not feel like it
 - Life event: e.g. death in the family, move, new job etc
 - Other medication
 - Used a friends' gel or tablet

Adherent?

- Yes
 No

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<p>16. Specific non-adherence examples</p> <p><u>ENGLISH:</u> Tell me about the last time you were not able to use the gel/tablets? (If always used): Tell me about the last time you almost were not able to use the gel/tablets.</p> <p><u>SESOTHO:</u> A ke o mpoelle ka nakong ya ho qetella moo o hlolehileng ho sebedisa jele/dipilisi? (Ha eba o e sebedisitse dinakong ka o fela): A ke o mpoelle ka nakong ya ho qetella moo o batlileng ho hloleha ho sebedisa jele/dipilisi?</p> <p><u>ISIZULU:</u> Ngitshele ukuthi kugcine nini ukuthi ungakwazi ukusebenzisa ijel/amaphilisi akho? (Uma uhlala uwasebenzisa): Ngitshele ukuthi kugcine nini ukuthi ucishe ungakwazi ukusebenzisa ijel/amaphilisi?</p> <ul style="list-style-type: none"> • What was going on? • What were the circumstances? Provide details of where, when, how, who was there, what happened • How often do these circumstances happen? What made it not possible to use last time, but possible to use another time? 		
<p>17. Does perceived efficacy influence adherence?</p> <p><u>ENGLISH:</u> What do you think the gel/tablets do to your body? And how does this influence your decision to take the gel/tablets?</p> <p><u>SESOTHO:</u> O nahana hore jele/dipilisi di etsa eng mmeleng wa hao? Le hona se se o susumetsa jwang sephetho sa hore o sebedise jele/dipilisi?</p> <p><u>ISIZULU:</u></p>	<p>Perceived efficacy influence adherence?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>	

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<p>Ucabanga ukuthi ijel/amaphilisi enzani emzimbeni wakho? Ingabe lokho kunomthelela onjani kwisinqumo sakho sokuthatha ijel/amaphilisi?</p> <ul style="list-style-type: none"> • Protect against HIV • Cleanses the womb • Revitalises the body • Energises the body • Makes you sick/weaker • Makes you feel like you are HIV infected (taking treatment) • Makes you feel dirty 		
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STUDY PRODUCTS AND RISK TAKING BEHAVIOR

<p>18. Does gel/tablets use influence sexual behaviours , relationships and contraception?</p> <p><u>ENGLISH:</u> Since you have been using the gel/tablets have you changed your sexual behaviours, relationships and use of contraception?</p> <p><u>SESOTHO:</u> Ha esale o sebedisa jele/dipilisi o ile wa fetola boitswaro a tsa hao a tsa thobalano, dikamano, le tshebediso ya thibela-pelehi?</p> <p><u>ISIZULU:</u> Selokhu wasebenzisa ijel/amaphilisi, ingabe sewushintshile yini ukuziphatha kwakho kwezocansi, kwezobudlelwane, nasekusebenziseni uhlelo lomndeni?</p> <ul style="list-style-type: none"> • Anal or oral sex • Condom use • Contraception • Type or number of sexual partners 	<p>Products change sexual behaviour?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> Somewhat</p> <p><input type="checkbox"/> No</p>	
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| <ul style="list-style-type: none"> • How often you have sex • Reasons for having sex (transactional sex, for pleasure, procreation) | | |
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VAGINAL PRACTICES AND PRODUCT PREFERENCES

<p>19. Does gel/tablets use influence hygiene and vaginal cleaning practices?</p>		
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ENGLISH:

Since you have been using the gel/tablets have you changed your hygiene and vaginal cleaning practices?

SESOTHO:

Ha esale o sebedisa jele/dipilisi o ile wa fetola ditlwaelo tsa bohleweki le ditlwaelo tsa o hlwekisa setho sa bosadi?

ISIZULU:

Selokhu wasebenzisa ijel/amaphilisi, usuyishintshile indlela yokuzicoca neyokuhlanza isitho sakho sangasese?

- Do you find that you need to wash or clean your vagina more or less while on product? Why?
- Are you able to add gel/tablets use into their daily routine of hygiene and vaginal cleaning? If yes, how do you manage?
- After joining the VOICE study, what happened to vaginal cleansing practices before or after sex? Did anything change?
- Does counselling from the study influence these practices?

Products change vaginal practices?

- Yes
 Somewhat
 No

<p>20. Did preferences develop over gel vs. tablets?</p>		
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ENGLISH:

Do you prefer to be on the gel or the tablets?

Product preference?

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<p><u>SESOTHO:</u> E kaba o thabela ho sebedisa jele kapa dipilisi?</p> <p><u>ISIZULU:</u> Ukhetha ukusebenzisa ijel noma amaphilisi?</p> <ul style="list-style-type: none"> • Did your preference change since you started the VOICE study? • Does the gel do things to the body that the tablets don't (or vice versa)? • What are the advantages/disadvantages of daily tablet taking vs. daily gel use? • Discuss issues surrounding discreteness and female-initiation for gel versus tablets • Did you ever try the other product and exchange tablets for gel? 	<ul style="list-style-type: none"> <input type="checkbox"/> Gel preferred <input type="checkbox"/> Tablets preferred <input type="checkbox"/> No clear preference 	
<p>21. Any other questions?</p> <p><u>ENGLISH:</u> Is there anything else you would like to tell me about the study products or your experience using the gel/tablets?</p> <p><u>SESOTHO:</u> E kaba ho na le se seng hape se o ratang ho bua le nna sona ka ha dihlahiswa tsa dipatlisiso kapa boiphihlelo a haho ka tshebediso ya jel/dipilisi?</p> <p><u>ISIZULU:</u> Ingabe ikhona enye into ongathanda ukungitshela yona ngemikhigizo yocwaningo, noma isipiliyoni sakho sokusebenzisa ijel/amaphilisi?</p> <ul style="list-style-type: none"> • Ask if they have any questions for you 		

<p>TO BE COMPLETED BY INTERVIEWER AFTER IDI COMPLETED:</p> <p>General comments about mood, how the interview went, participant's level of comfort/openness etc...</p>	<p>General flow of this FGD:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Easy <input type="checkbox"/> Difficult <p>Participants were comfortable and talked easily?</p> <ul style="list-style-type: none"> <input type="checkbox"/> All <input type="checkbox"/> Some <input type="checkbox"/> None 	
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