INSTRUCTIONS for the facilitator to understand – How to read this Focus Group Discussion 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.
   - FGD questions: the questions that you as the facilitator will ask respondents in order to get answers to the research questions.
   - Probes: they are indicated with a bullet, and will not be translated. The facilitator should ensure that key topics listed in the probes have been addressed/discussed during the FGD. So, depending on what has already been discussed, and the FGD context, you may ask these probes or not.

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 questions and instructions. The FGD 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 FGD. You may adapt the question, depending on how the discussion develops. The facilitator will have to ensure that at the end of the discussion, the research questions have been answered.
   - The middle column is for questions for which there is likely to be consensus and a clear response from the group. Please check the response options that best captures the group response to the research question.
   - The right-hand column is for summarising the themes. These should be summaries of the general issues raised in connection with the research question, NOT responses of individual women in response to particular points or questions. These summaries should be more than just yes/no, but not longer than a few sentences of bullet points. They do not need to be detailed, as we have the details on the tape. Note: the summaries and yes/no answers can be filled during the FGD by the note-taker, and then reviewed immediately after the FGD by the facilitator.

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 recorded today. Please verbally indicate that you are aware that we are tape recording this session and that it is okay with you. [Facilitator: be sure to get a verbal okay from all members of the focus group.]
<table>
<thead>
<tr>
<th>Date:</th>
<th>No. FGD_</th>
</tr>
</thead>
</table>

### 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 community and what has been the effect on VOICE participants?

**SESOTHO:**
Ke eng tse o di utwileng batho ba bua ka tsona ka ha dipatlisiso tsa VOICE mo motseng wa heno? Le hona se se amile jwang bankakarolo dipatlisisong tsa VOICE?

**ISIZULU:**
Uzwe abantu bethini ngocwaningo lwe VOICE kumphakathi wakho? Futhi lokho kube nomphumela onjani kubantu ababantwane iqhaza 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?

<table>
<thead>
<tr>
<th>Did rumours/ stories influence participants’ adherence to product and clinical procedures?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes</td>
</tr>
<tr>
<td>☐ No</td>
</tr>
</tbody>
</table>

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Staff Initials & Date_________
### 2. How did the local environment influence gel/tablets adherence?

**ENGLISH:**
What sorts of things about the area you live in helped or hindered women’s daily use of gel/tablets in the VOICE study?

**SESOTHO:**
Ke dintho tsa mofuta mang mo tulong eo o dulang ho yona tse thusitseng kapa tse sitetseng basadi ho sebedisa jele/dipilisi letsatsi le lestatsi mo dipatlisong 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?

---

<table>
<thead>
<tr>
<th>Influence of the environment on product use?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive influence</td>
</tr>
<tr>
<td>---------------------------------------------</td>
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</tbody>
</table>
### ORGANIZATIONAL FACTORS

#### 3. What motivated participants to join the VOICE study

**ENGLISH:**
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 ezisemgoka 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 transport
- Access 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?

**ENGLISH:**
What information or messages did you receive from the clinic staff on how to use gel/tablets?

<table>
<thead>
<tr>
<th>Accurate understanding of product use?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Mostly</td>
</tr>
<tr>
<td>☐ Some</td>
</tr>
<tr>
<td>☐ Little/none</td>
</tr>
</tbody>
</table>

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Date:  /  /  
No.  FGD_  

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**VOICE-C**

**FOCUS GROUP DISCUSSION GUIDE: Group 1**

**SESOTHO:**
Ke lesele lefe kapa melaetsa efe eo basebeletsi ba kliniking ba o fileng, ya hore o sebedise jwang jele/dipilisi?

**ISIZULU:**
Ingabe yiluphi ulwazi noma imilayezo oyitholile kubasebenzi basemotholampilo mayela nokuthi isetyenziswa kanjani jel/amaphilisi?

- 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?

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</tbody>
</table>

Date: □□/□□/□□

No. FGD_□□□

□ No consensus
Comfortable reporting accurate product use?
- Very
- Not very
- Not at all

Staff Initials & Date_________
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 neje/nejel amaphilisi abantu besifazane abaxoxisana ngazo nabanye. Futhi ingabe lokho kube nomthelela ekusetshenzisweni kwemikhiziqo?

- 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?

________________

________________
### 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 mofutu 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 nomza zenza kwabe nzima ukufaka jel 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
### 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/dipiliisi hantle?

**ISIZULU:**
Ingabe abantu ohlala nabo (ngaphandle komyenzi /uphathini wakho) babe namuphi umthelela ngokusetshenziswa kahle kweje/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?
### 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 izingumo malunga nokuya ofansini, 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?
9. Did male partners influence product adherence?

**ENGLISH:**
How did male partners influence the way women used the **gel/tablets**?

**SESOTHO:**
Balekane ba ba batona ba ne ba susumeditsa jwang ka tsela eo basadi ba neng ba sebedisa jele/dipilisi?

**ISIZULU:**
Ingabe abangane besilisa babe nomthelela onjani kwindlela abesifazane abasebenzise ngayo ijeI/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)

<table>
<thead>
<tr>
<th>Partners generally supportive of product use?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Yes</td>
</tr>
<tr>
<td>□ No</td>
</tr>
<tr>
<td>□ No consensus</td>
</tr>
</tbody>
</table>

| □ Yes |
| □ No |
| □ No consensus |

| □ Yes |
| □ No |
| □ No consensus |
**10. Were male partners generally supportive of study participation?**

**ENGLISH:**
How did male partners influence whether women joined the VOICE study?

**SESOTHO:**
Balekane ba batona ba bile le susumetso jwang hore basadi ba kene kapa ba se kene dipatlisong tsa VOICE?

**ISIZULU:**
Abangane besilisa babe nomthelela onjani ekutheni abesifazane bangene noma bangangeni kucwaningo lweVOICE?

- 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)
### 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:**
Yini beyikhathaza abalingani besilisa mayelana nokuthi abalingane babo besifazane basebenzisa jel/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.

<table>
<thead>
<tr>
<th>Male partners’ main concern:</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Themselves</td>
</tr>
<tr>
<td>☐ Female partner</td>
</tr>
<tr>
<td>☐ No consensus</td>
</tr>
</tbody>
</table>

No consensus
**VOICE-C**  
**FOCUS GROUP DISCUSSION GUIDE: Group 1**  

**ACCEPTABILITY**

### 12. Were the gel/tablets generally acceptable to participants?

| ENGLISH: What did women in the VOICE Study like and dislike about the gel/tablets? |
|---------------------------------|--------------------------------------------------|

| SESOTHO: Ke eng seo basadi dipatlisisong tsa VOICE ba neng o se rata kapa o sa se rate ka jele/dipilisi? |
|---------------------------------|--------------------------------------------------|

| ISIZULU: Yikuphi abesifazane abakucwaningo IweVOICE 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?
### 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 jele/diplisi letsatsi le letsatsi kapa tje?

**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 something else?

| Consistently used? |  
|-------------------|---|
| Yes               |  
| No                |  
| No consensus      |  

---

**NOTE:**
- Consistently used? (Yes/No/No consensus)
## 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?

**SESOTHO:**
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?

**ISIZULU:**
Ingabe yiliphi izinga lokusetshenziswa kahle (nsuku zonke) komkhigizo elingalindlwa kwimpilo yeniwayelo, uma abesimame bebengasebenzisa *i jel/amaphili s isicwania ngikhulisana isandulela ngculazi, ngaphandle kokubamba iqhaza ku swapingo?*

- 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…)
# Study Products and Risk Taking Behaviour

## 15. Did gel/tablets use influence sexual behaviours, relationships and contraception?

<table>
<thead>
<tr>
<th>English: How did gel/tablets use change women’s sexual behaviours, relationships, and use of contraceptives during the VOICE study?</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Sesotho: Na tshebediso ya jele/dipilisi e fetotse maitschwaro o tsa thobalano ya basadi, dikamano, le tshebediso ya dithibelapelehi ka nako ya mo dipatlisiso tsa VOICE?</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Isizulu: Ukusebenzisa ijelemaphilisi kukushinshe njani ukuziphatha kwabesifazane mayela nezocansi, ubungane, ukusebenzisa uhlelo lomndeni ngesikhathi bekucwaningo lweVOICE?</th>
</tr>
</thead>
</table>

- 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?

### Products changed sexual behaviours?
- **Yes**
- **Somewhat**
- **No**
# FOCUS GROUP DISCUSSION GUIDE: Group 1
## VAGINAL PRACTICES & PRODUCT PREFERENCE

### 16. Did gel/tablets use influence hygiene or vaginal cleansing practices?

<table>
<thead>
<tr>
<th>ENGLISH:</th>
<th>Products changed vaginal practices?</th>
</tr>
</thead>
<tbody>
<tr>
<td>While you were using the gel/tablets did you change your hygiene and vaginal cleansing practices?</td>
<td>□ Yes □ No □ No consensus</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SESOTHO:</th>
<th>Products changed vaginal practices?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ha ne o sebedisa jelé/dipilisi o ile wa fetola ditlwaelo tsa bohlweki le ditlwaelo tsa o hiwekisa setho sa sesadi?</td>
<td>□ Yes □ No □ No consensus</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ISIZULU:</th>
<th>Products changed vaginal practices?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ngesikhathi usebenzisa jelé/amaphilisi uye washinsha indlela yokuzicoca neyokuhlanza isitho sakho sangasese?</td>
<td>□ Yes □ No □ No consensus</td>
</tr>
</tbody>
</table>

- 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?
17. Did preferences develop among the women over gel vs. tablets?

**ENGLISH:**
Was either the tablets or the gel perceived to be more preferable among the women in the VOICE study?

**SESOTHO:**
Ekaba mahareng ha jele le dipilisi ho na le eo e neng e bonahala e thabelwa haholo hara basadi mo dipatlisisong tsa VOICE?

**ISIZULU:**
Ingabe bekuyi j nel nomaphilisi 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)?

<table>
<thead>
<tr>
<th>Product preference?</th>
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<tbody>
<tr>
<td>□ Gel preferred</td>
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<td></td>
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<tr>
<td>□ Tablets preferred</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ No clear preference</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Product preference?**

- Gel preferred
- Tablets preferred
- No clear preference
### 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?

**SESOTHO:**
Ekaba ho na le se seng hape se le ratang ho bua le nna sona ka ha dhlahiswa tsa dipatlisiso kapa maiphihlelo a lena ka tshebediso ya jele/dipilisi?

**ISIZULU:**
Ingabe ikhona enye into ongathanda ukungitshela yona ngemikhizolo 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…

<table>
<thead>
<tr>
<th>General flow of this FGD:</th>
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<tbody>
<tr>
<td>□ Easy</td>
</tr>
<tr>
<td>□ Difficult</td>
</tr>
<tr>
<td>Participants were comfortable and talked easily?</td>
</tr>
<tr>
<td>□ All</td>
</tr>
<tr>
<td>□ Some</td>
</tr>
<tr>
<td>□ None</td>
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</tbody>
</table>