RIHES, Chiang Mai
Update for MTN-017

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Presentation Outline

- Recruitment activities and Education
- Study progress
- Challenges, Strategies and Lesson learned
World AIDS day
MSM NGO
Website www.pimancenter.com
Clinic
Physical Exam Room
## Study Progress

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>Date of activation</td>
<td>Jan 6, 2014</td>
</tr>
<tr>
<td>First Screening</td>
<td>Jan 16, 2014</td>
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<tr>
<td>First Enrollment</td>
<td>Feb 4, 2014</td>
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</tbody>
</table>
Study Progress (Screened and Enrolled)

- Number participants screened
  - 16 persons

- Number participants enrolled
  - 5 persons

- S:E ratio
  - 2.2 : 1 (11:5)

- Retention numbers
  - N/A
Screened and Enrolled

- Screened 16
  - Enrolled 5
  - Ineligible 6
  - Waiting lab result 3
  - Met eligibility criteria 2
    and plan to enroll
    total 16
Ineligible cases reasons

- ALT grade 1
- WBC high
- Rectal CT positive
- HIV positive
- Symptomatic anal wart

Plan re-screen
Challenges, Strategies and Lesson learned
Recruitment

- Provide MTN017 Study Information to MSM community and CAB meeting
- Persuade targeted participants to visit PIMAN clinic and show them study equipment and explain all processes to be performed there.
- Present Microbicide Video
Study Introduction for Targeted Participant

- Review study process and ICF summary
- Show a sample of study drug and some study equipment.
- Discuss about possibility for follow up every months
- Suggest the possibility of problems when using study product (i.e. obstacles, family problem, partner problem)
- If interested in joining, then make an appointment date
Pharmacy Update

- No problem for process but participant concerns about the size of Tenofovir gel bag that is too big!
Eco Bag
Behavioral Update

- CASI Administration: No problem
- SMS System: *Not alert on weekend*
- PK Data and Data Convergence Interviews: Not yet
- In-Depth Phone Interview: Not yet
Behavioral Update

- SMS System

During the weekend, a participant called to clinic staff that he had not received SMS. Nurse instructed him to try by sending password to alert the system, after done that he received SMS and start to do as usual. This problem happened again in the next day. So, he did the same.

The site consulted to Rebecca and she suggested that what we did is correct because sometimes system has error bug.

From this event, clinic staff has informed all participants how to do when this problem happens.
Study Product Instruction, SMS Instruction and ICF Booklet
SMS instruction
TRUVADA daily
Tenofovir Gel daily
RAI Tenofovir Gel
Laboratory Update

- All laboratory test has completed as requirement.
- One case was forgot to do pre-weighted rectal sponge.
  - Normally, clinic staff will send cryovial tube with sponge per case to laboratory for pre-weighted.
  - By accidentally, clinic staff took a sponge that had not yet pre-weighted to collect rectal PD.
Resolution

- Create a checklist for equipment preparation and specimen collection kits.
- Keep separately sponge that not pre-weight in another room.
- Keep sponge individually per case in each box.
- Add to perform QC pre-process, previously we have only QC post process.
- Re-train the procedure of specimen collection.
PD and PK package
### Rectal Exam Checklist

**Procedures**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>SCR</th>
<th>Period 1</th>
<th>Period 2</th>
<th>Period 3</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review chart notes and other relevant documentation</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
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<tr>
<td>Prepare exam equipment, documentation, and specimen collection supplies</td>
<td>x</td>
<td>x</td>
<td>x</td>
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<td>x</td>
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<tr>
<td>Explain exam procedures to participant and position participant</td>
<td>x</td>
<td>x</td>
<td>x</td>
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<tr>
<td>Perform visual/perianal exam</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
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<tr>
<td>Collect rectal swab for HSV1/2 testing if indicated</td>
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<tr>
<td>Collect anal swab for HPV typing</td>
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<tr>
<td>Perform digital rectal examination</td>
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<tr>
<td>Prepare anoscope for specimen collection per SSP section 8.5.1</td>
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<tr>
<td>Evaluate for abnormalities. Document findings on Anorectal Exam CRF</td>
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<tr>
<td>Collect rectal swab for GC/CT testing</td>
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<tr>
<td>Collect the rectal sponge for adherence PK</td>
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<tr>
<td>Collect the rectal sponge for PD</td>
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<tr>
<td>Slowly remove anoscope, if applicable</td>
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<tr>
<td>Evaluate any abnormal findings. Refer for/provide treatment if needed</td>
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</table>

**Only if Indicated**

- Collect rectal swab for HSV1/2 testing
- Collect anal swab for HPV typing
- Collect rectal swab for GC/CT testing
- Collect the rectal sponge for adherence PK
- Collect the rectal sponge for PD.
Rectal Specimen collection flowchart

1. Explain exam procedures and position to participant
2. Perform visual/perianal exam
3. Collect rectal swab for HSV 1/2 testing (*if indicated*)
4. Collect anal swab for HPV typing (enrollment only)
5. Digital rectal examination
6. Prepare anoscope
7. Rectal swab for GC/CT Screen, Enroll, End
8. Rectal sponge for PD (Enroll, Mid, End)
9. Rectal sponge for adherence PK (Mid, End)
Counseling Update

- **Adherence counseling:** Currently, we are at the enrollment process and not reach follow up visit yet.

- **Product use instruction:** It is difficult for RAI case. So, participants will be suggested to use project’s appointment card which has calendar to record the date that gel was used.
Thank you