Key issues Prepex Study Zimbabwe
Enrolment into the Prepex study

**Inclusion criteria all phases**

- Above 18 years
- HIV sero-negative
- Agreed to be circumcised by any of the study methods, PrePex or Surgical
- Accepted study procedures and requirements
  - Agreed to return to the healthcare facility for follow-up visits (or as instructed) for up to 10 weeks post-procedure
  - Agreed to anonymous video and photographs of the procedure
  - Agreed to in-depth psychosocial interviews.
  - Abstain from sexual intercourse and directly rubbing circumcised area (e.g. masturbation),

**Sample size**

- **Phase 1:** 53
- **Phase 2:** 160
- **Phase 3:** 603
- **Extended phase for PCN:** 600
Eligibility for the Device

- The majority of men in Zimbabwe were eligible for the device.
- 6% of men above 18 **not eligible** for the device.
- Main reason were:
  - Phimosis
  - Penile size bigger than available sizes. This was not significant issue as only 3 men could not be placed with the device.
Adverse events

- Through the different phases of the study there were no severe adverse events, however acknowledge that TAG classified some as SAE.
- Below 1% of clients experienced mild to moderate adverse events.
- Odour was not systematically documented.
- Client behaviour was a contributing factor to some adverse events especially those that related to device displacement and early removal.
Acceptability

- Interviews conducted before placements at 2 weeks and 90 days post device placements.
- Men who had the device reported to have talked to about 20 people about the device circumcision compared to 10 in the surgical arm. (proxy)
- Device was also preferred by service providers as there were less calls compared to the surgical arm.
- Preference for device over surgery is apparent. More men currently not taking MC till device is available especially in sites that have provided device before
- Over 90% of Men reported being extremely satisfied with device and also reported they believed their sexual partners were also very satisfied
- The device did not affect the activities of daily living through all the phases of the study.
Men in device arm told more friends

Average number of people talked to about circumcision

- PrePex
- Surgery

- pre
- 2 weeks
- 90 days
**Effects on ADL**

- Generally No effect on daily activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>Strongly disagree</th>
<th>Perception pre placement</th>
<th>2 week Post placement</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work</td>
<td>73%</td>
<td>88%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bath</td>
<td>84%</td>
<td>87%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Socialise</td>
<td>92%</td>
<td>95%</td>
<td></td>
<td></td>
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<tr>
<td>Home Chore</td>
<td>90%</td>
<td>98</td>
<td></td>
<td></td>
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<tr>
<td>Sex with wife</td>
<td>48%</td>
<td>52%</td>
<td>38%/36</td>
<td></td>
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<tr>
<td>Urinate</td>
<td>85%</td>
<td>95%</td>
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</tbody>
</table>
Acknowledgements

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Thank you